APPENDIX TABLES

DHEA MEDICAL REVIEW

(note: Tables 1 and 6 are in the body of the review)

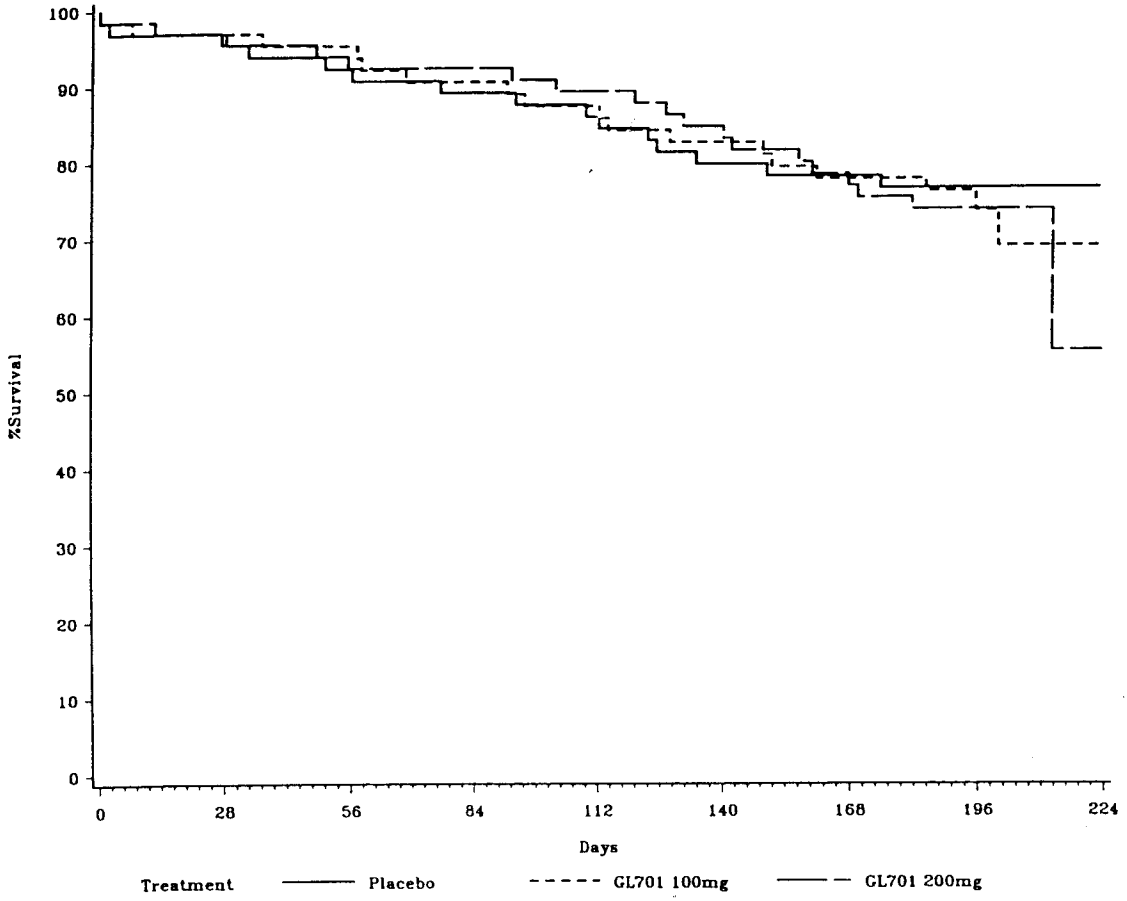
TABLE 2

A) Study GL94-01: Survival analyses for time to discontinuation for any cause

	Placebo	GL701 100mg	GL701 200mg
Discontinuation	15 (23.4%)	17 (7.0%)	17 (26.6%)
Completion	49	46	47
Total	64	63	64
P-value (GL701 vs. placebo)*		0.744	0.797

* LR test result based on SAS PHREG Procedure

Survival Curve for Early Termination of Study Medication for Any Cause



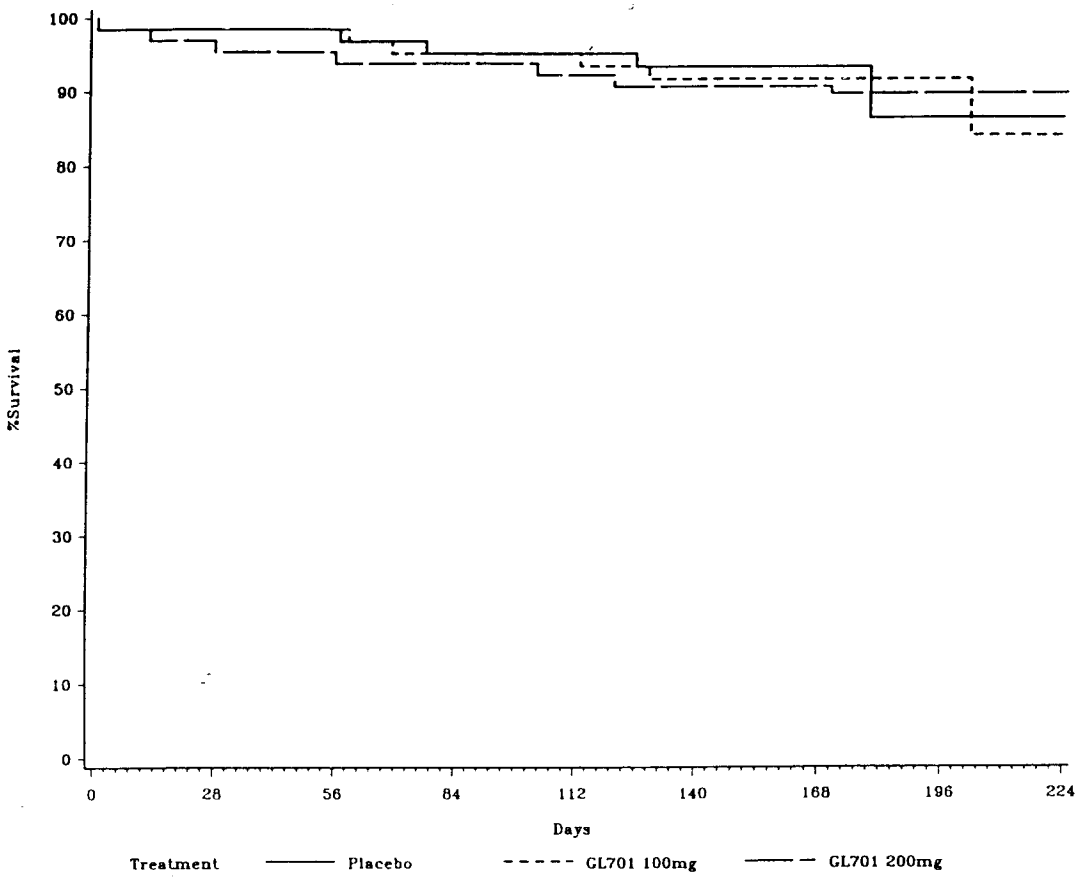
B) Study GL94-01: Survival analyses for time to discontinuation for adverse event

	Placebo	GL701 100mg	GL701 200mg
Discontinuation due to adverse events*	3 (4.7%)	4 (6.4%)	6 (9.4%)
Completion or discontinuation due to other causes	61	59	58
Total	64	63	64
P-value (GL701 vs. placebo)**		0.709	0.354

* Not related adverse events were included

** LR test result based on SAS PHREG Procedure

Survival Curve for Early Termination of Study Medication Due to Adverse Event



C) Study GL94-01: Survival analyses for time to discontinuation for lack of efficacy

	Placebo	GL701 100mg	GL701 200mg
Discontinuation due to lack of efficacy	7 (10.9%)	6 (9.5%)	5 (7.8%)
Completion or discontinuation due to other causes	57	57	59
Total	64	63	64
P-value (GL701 vs. placebo)*		0.765	0.504

* LR test result based on SAS PHREG Procedure

Survival Curves for Early Termination of Study Medication Due to Lack of Efficacy

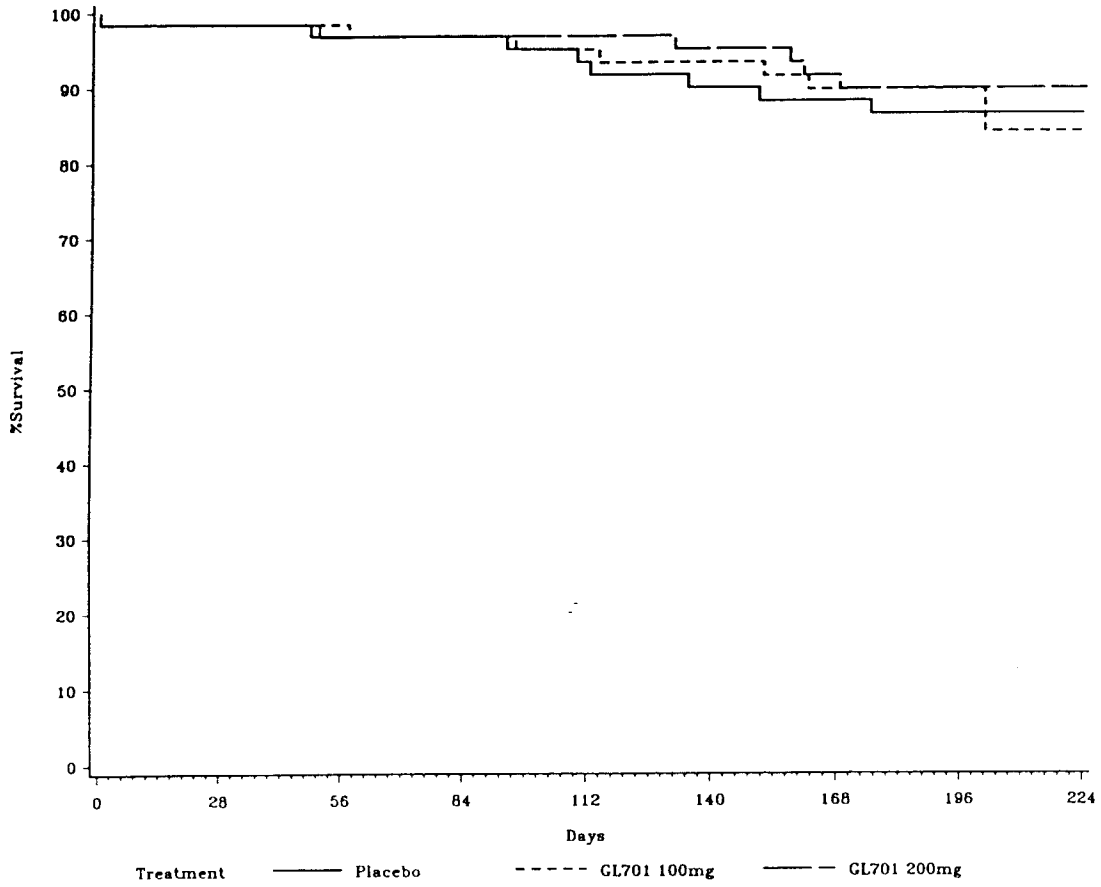


TABLE 3

Study GL94-01: Baseline SLEDAI Scores by Treatment Group

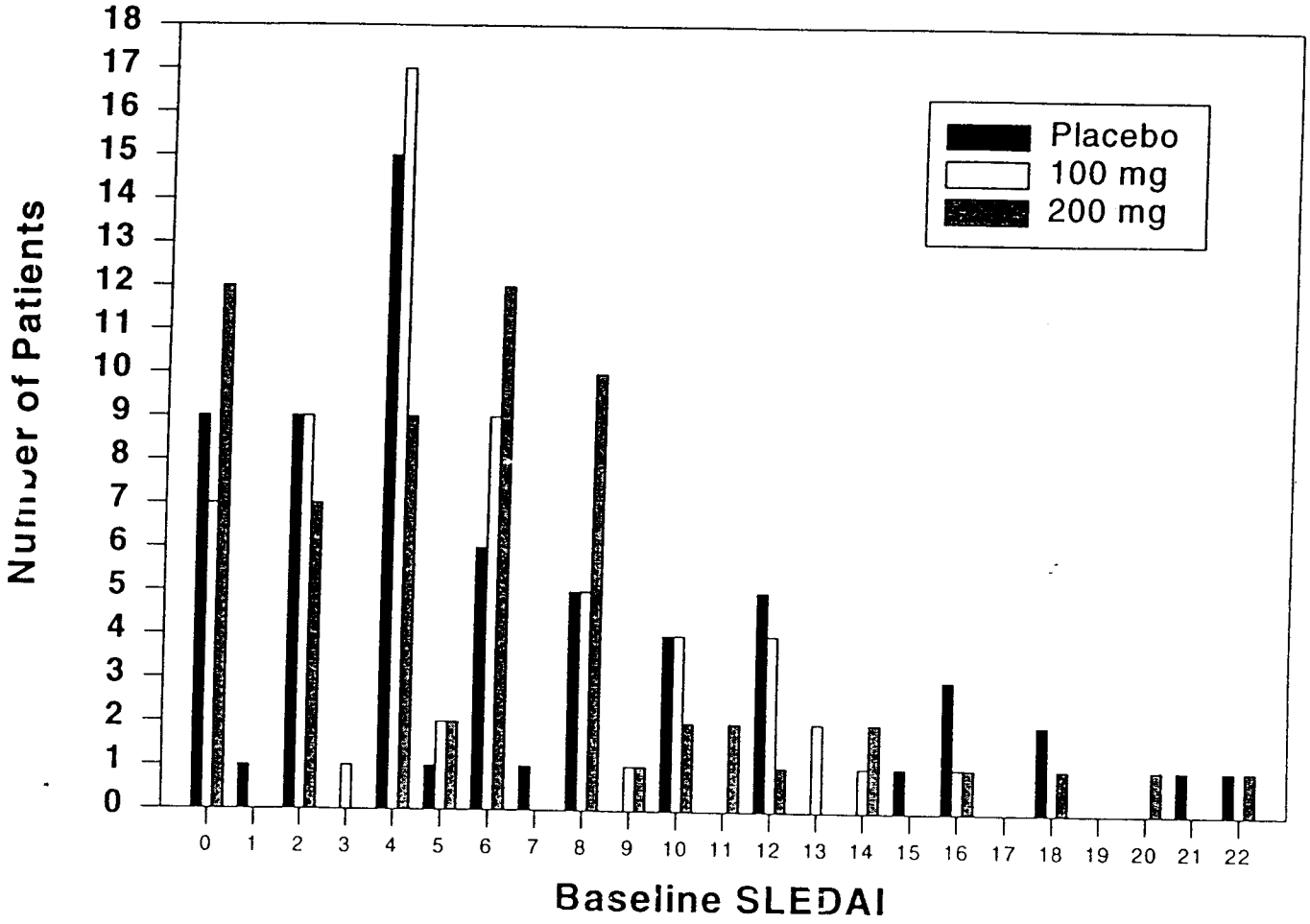
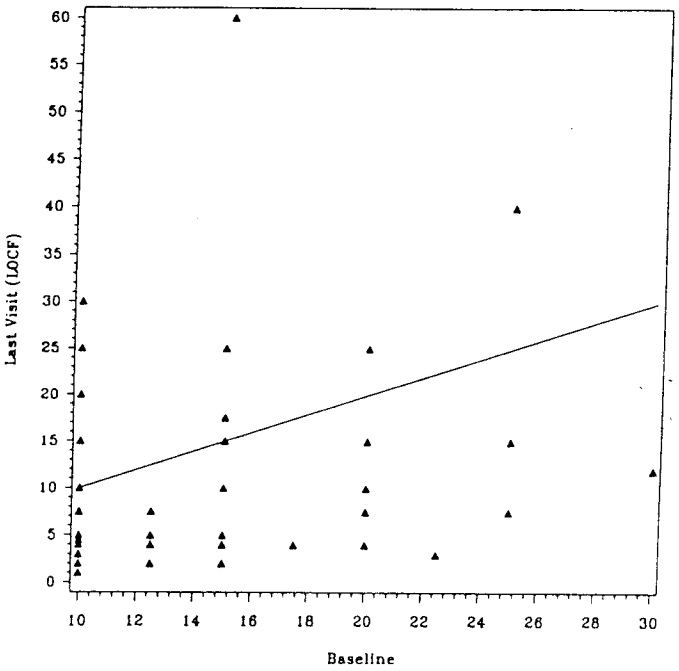
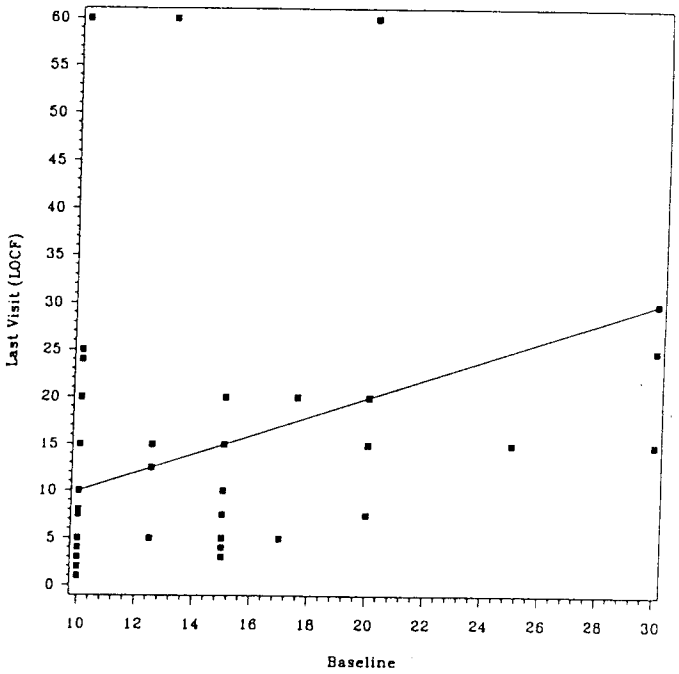


TABLE 4

Scatterplot of Actual Prednisone Dose (mg) at Baseline and Last Visit
Treatment Group: 200 mg



Scatterplot of Actual Prednisone Dose (mg) at Baseline and Last Vi
Treatment Group: 100 mg



Study GL94-01: Scatterplot of Actual Prednisone Dose (mg) at Baseline and Last Visit
Treatment Group: Placebo

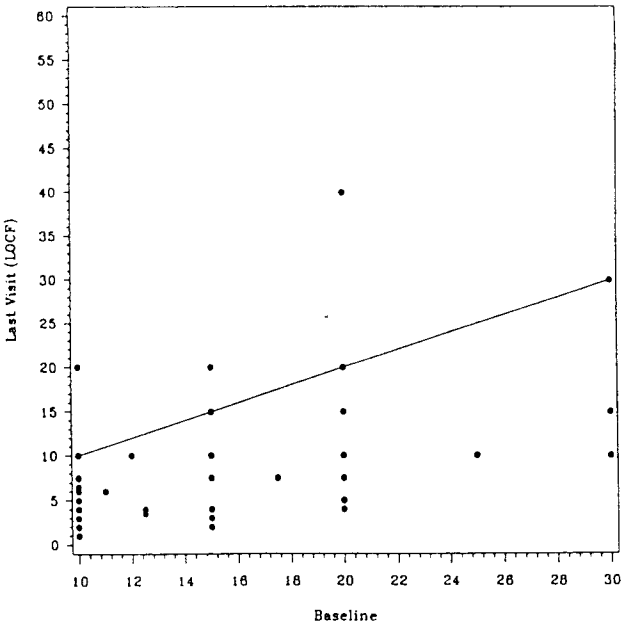


TABLE 5

Figure 9.5.2.5-7: Estradiol vs. DHEA-S by Responder at Baseline
(Placebo Patients)

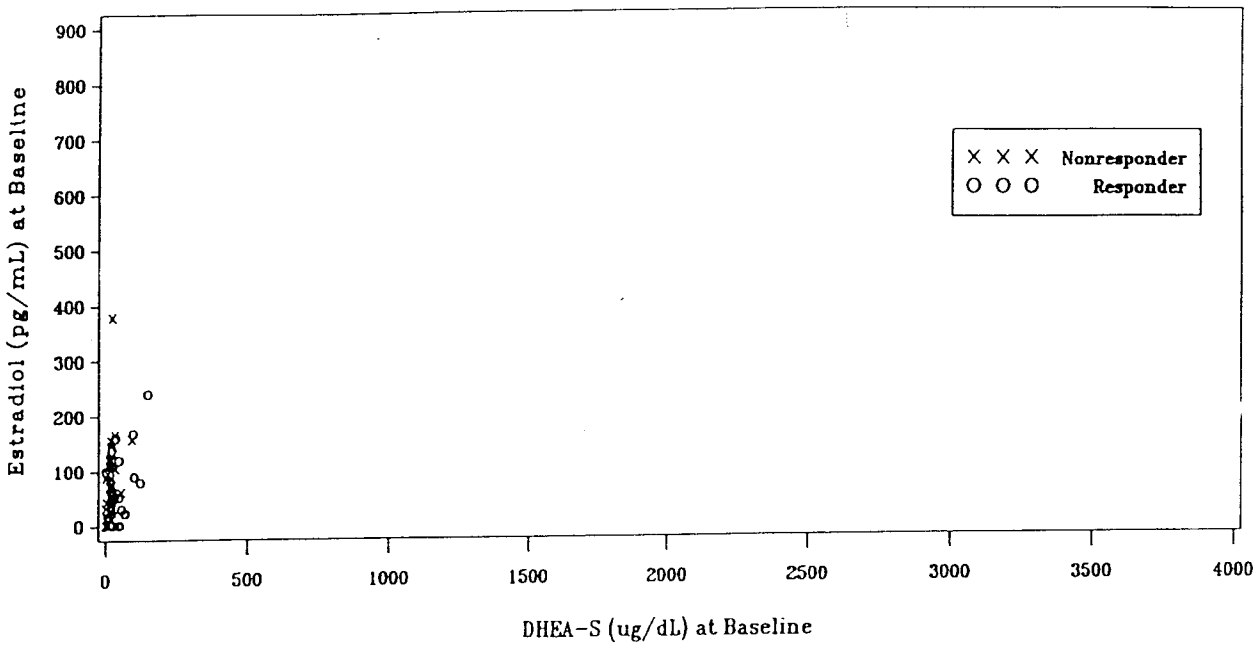
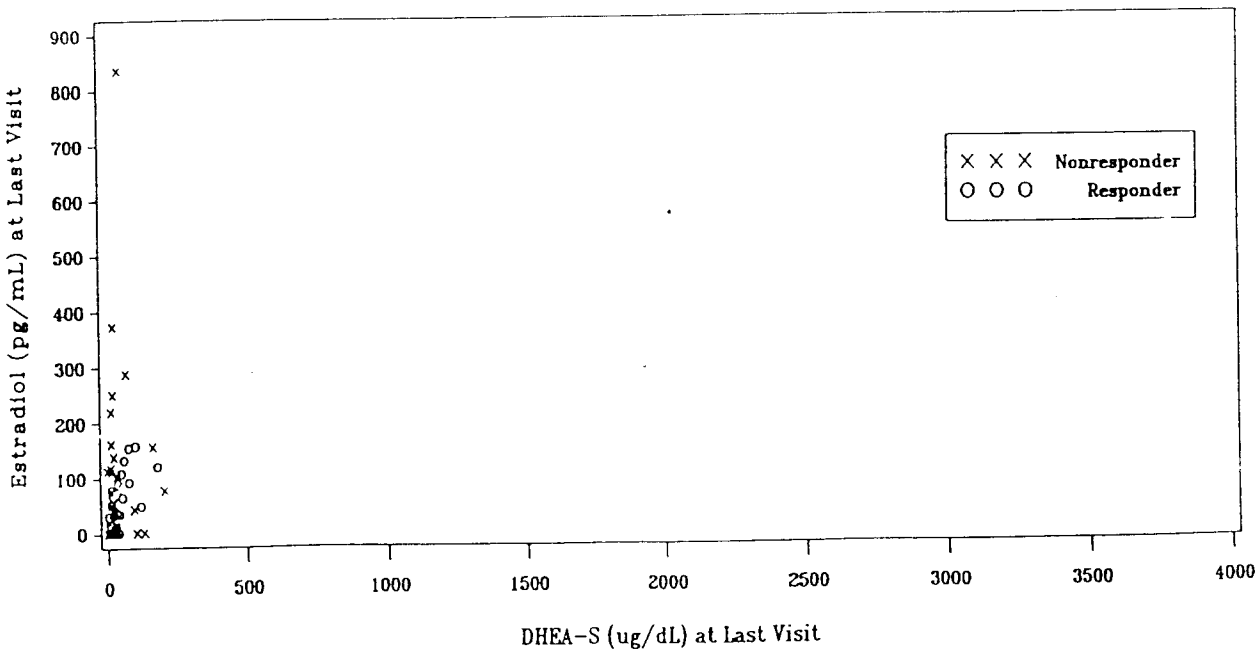


Figure 9.5.2.5-8: Estradiol vs. DHEA-S by Responder at Last Visit
(Placebo Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-9: Estradiol vs. DHEA-S by Responder at Baseline
(GL701 100mg Patients)

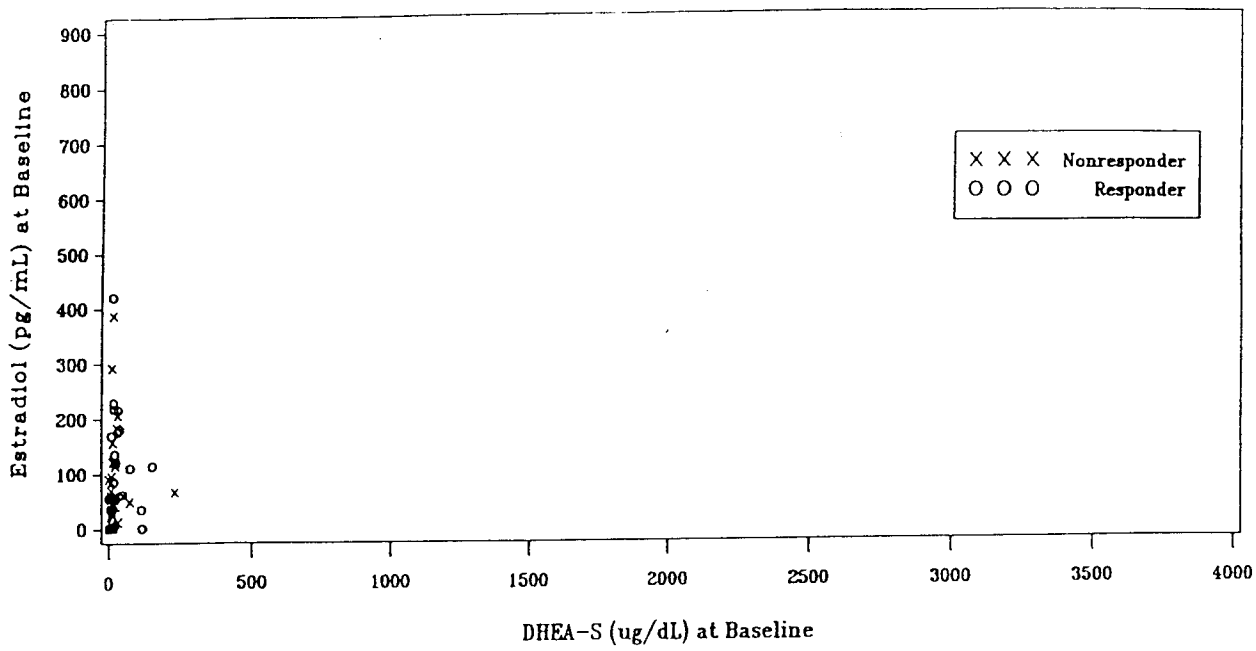
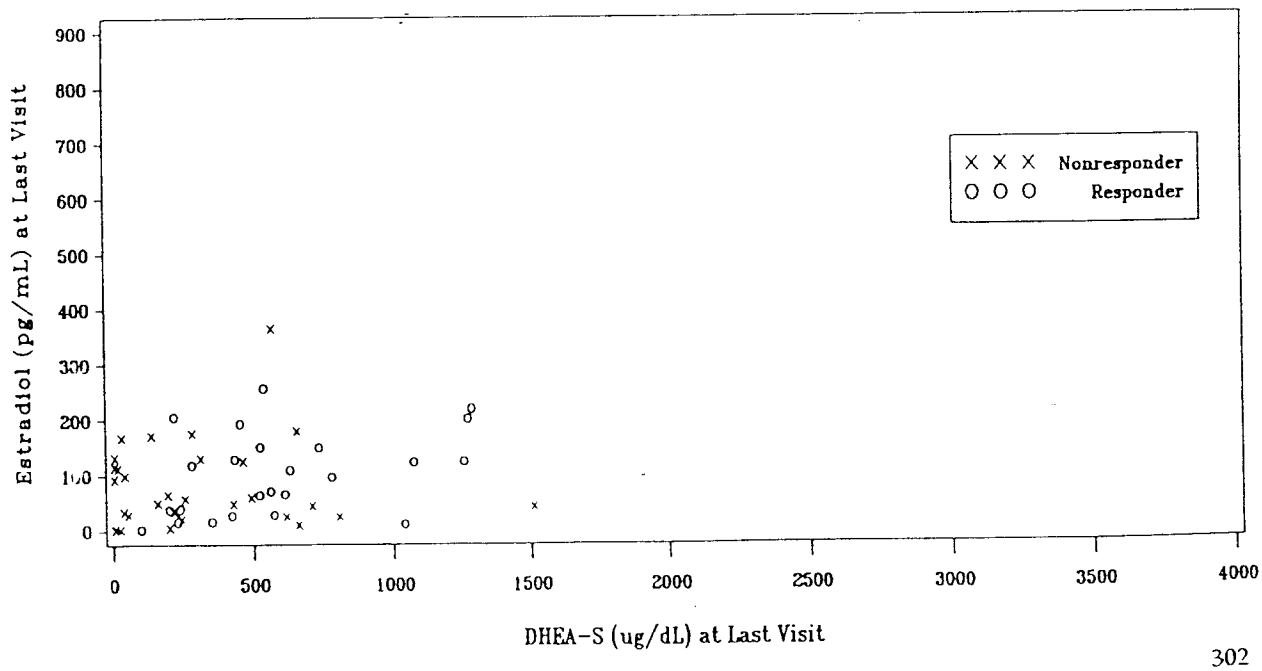


Figure 9.5.2.5-10: Estradiol vs. DHEA-S by Responder at Last Visit
(GL701 100mg Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-11: Estradiol vs. DHEA-S by Responder at Baseline
(GL701 200mg Patients)

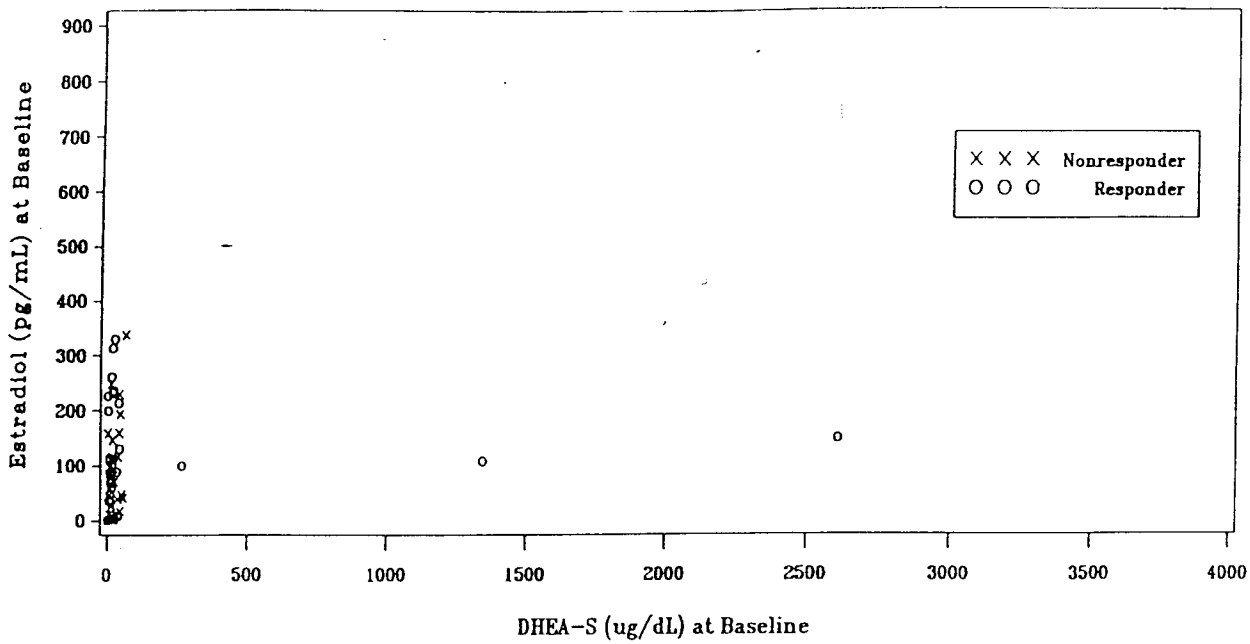
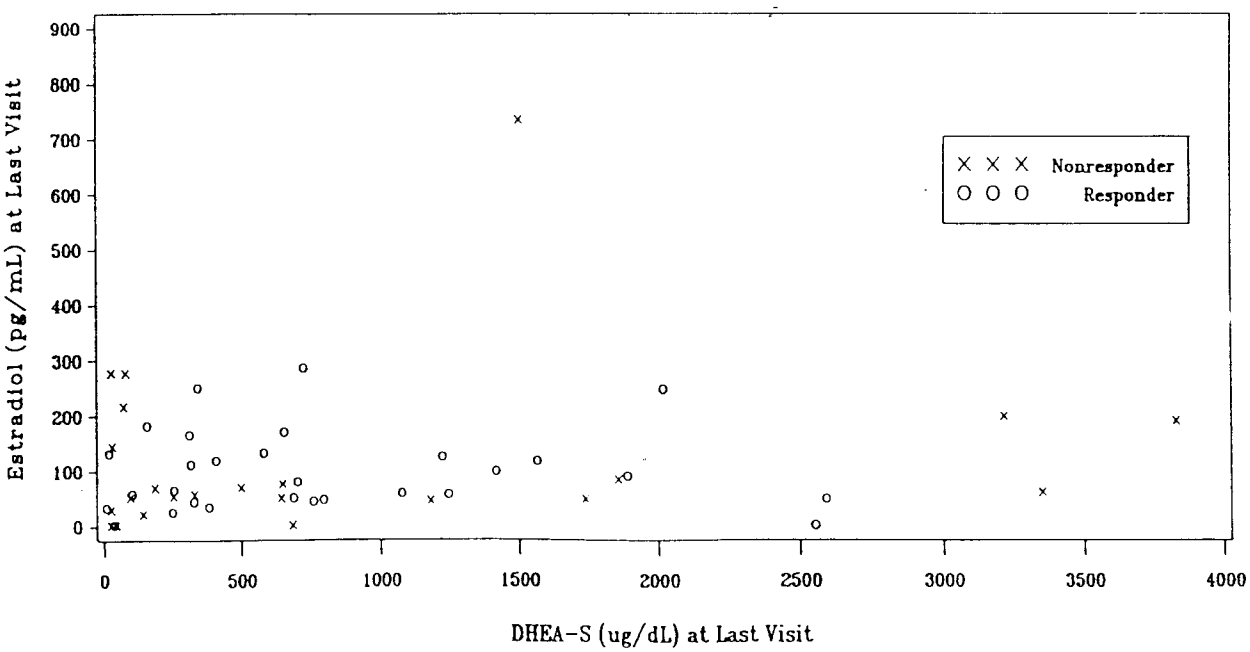


Figure 9.5.2.5-12: Estradiol vs. DHEA-S by Responder at Last Visit
(GL701 200mg Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-13: Testosterone vs. DHEA-S by Responder at Baseline
(Placebo Patients)

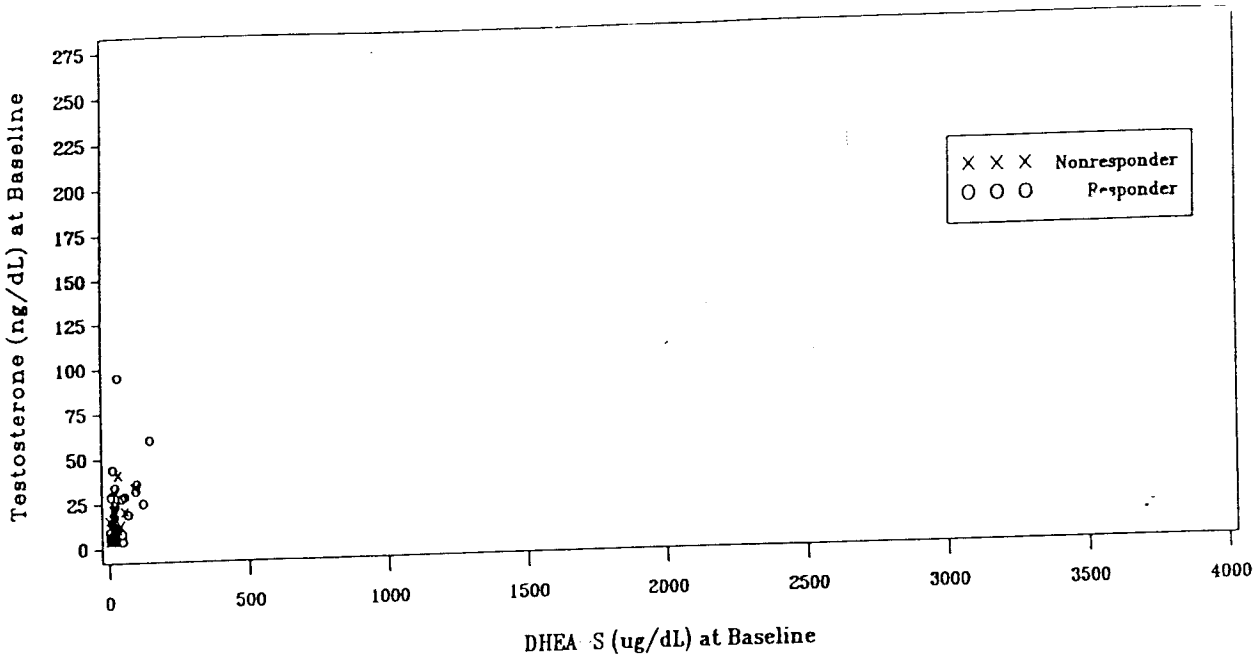
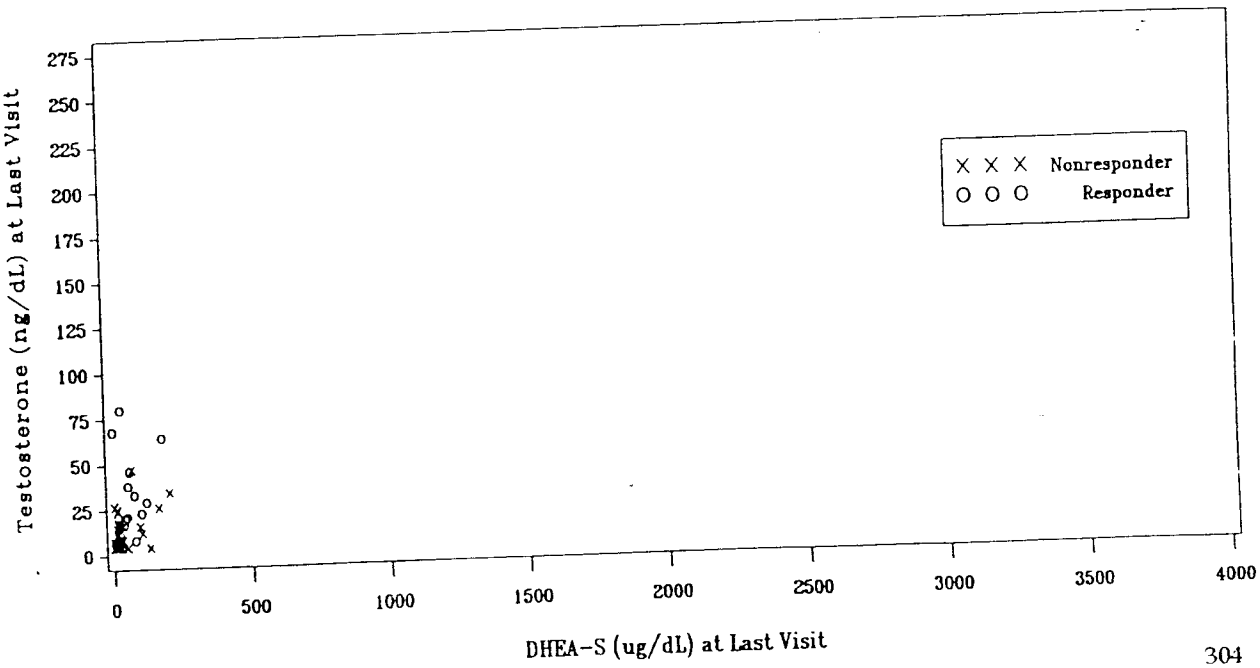


Figure 9.5.2.5-14: Testosterone vs. DHEA-S by Responder at Last Visit
(Placebo Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-15: Testosterone vs. DHEA-S by Responder at Baseline
(GL701 100mg Patients)

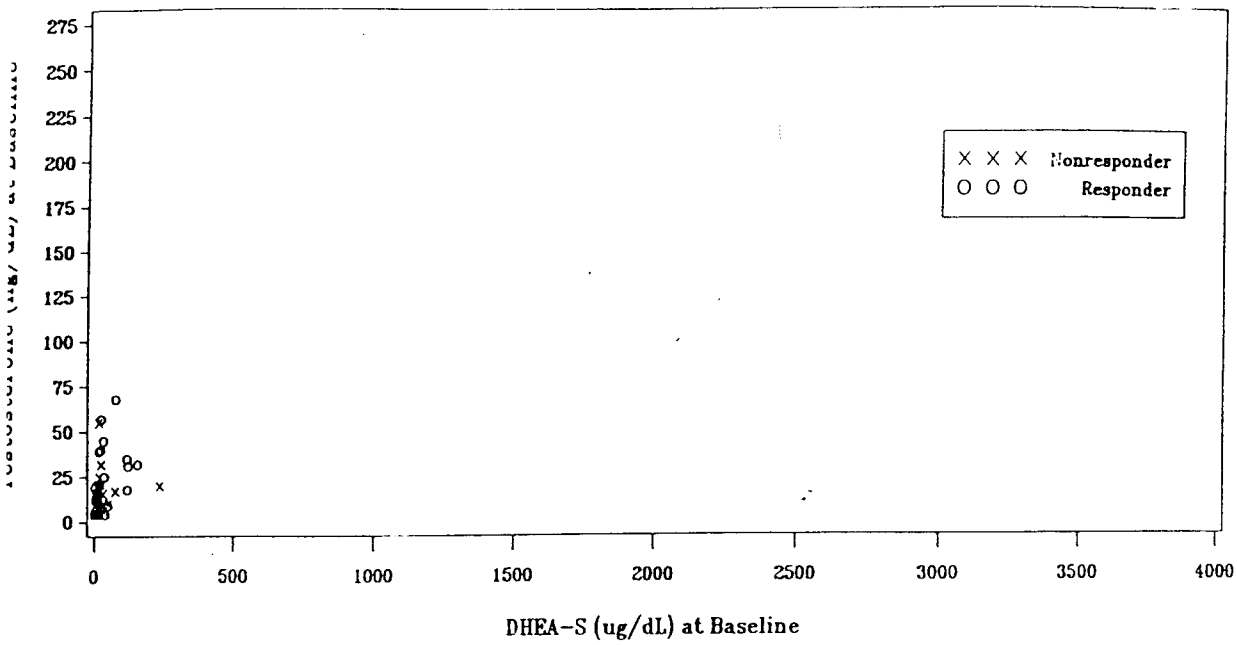
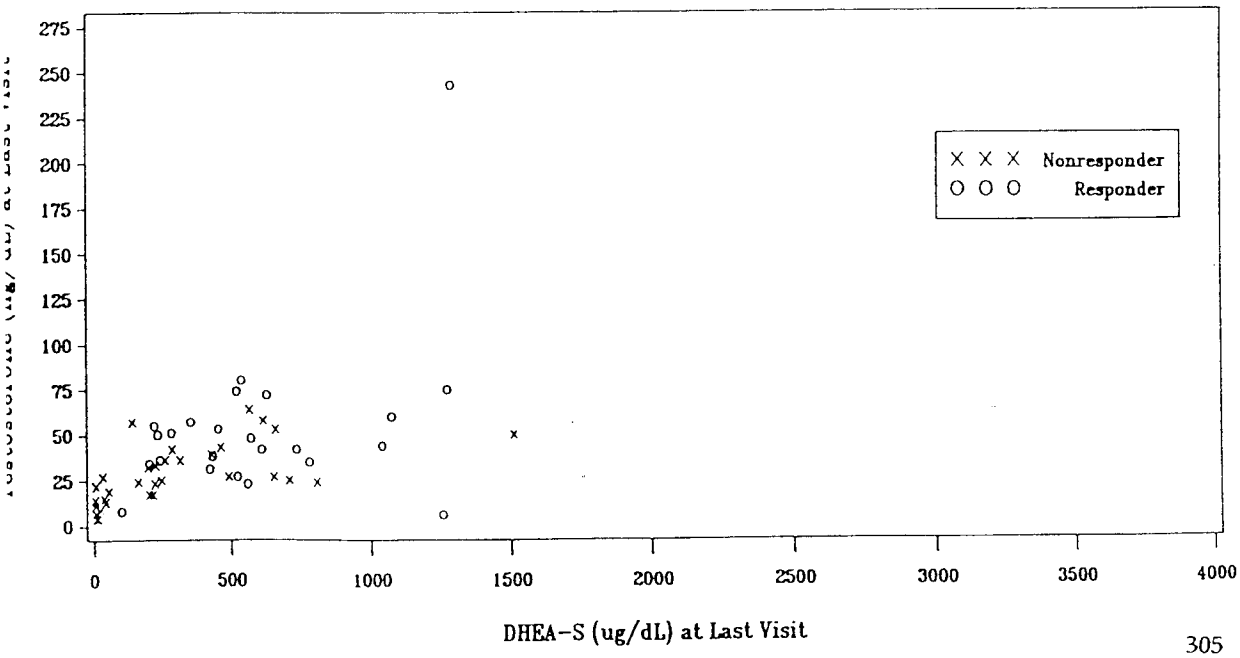


Figure 9.5.2.5-16: Testosterone vs. DHEA-S by Responder at Last Visit
(GL701 100mg Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-17: Testosterone vs. DHEA-S by Responder at Baseline
(GL701 200mg Patients)

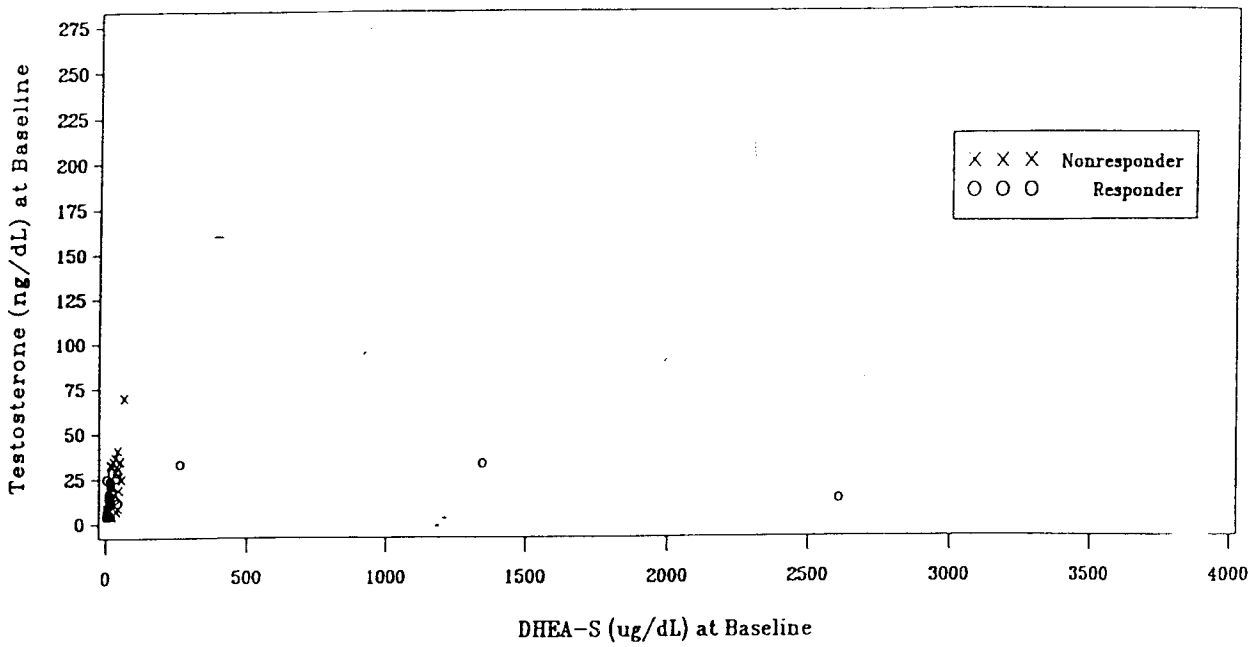
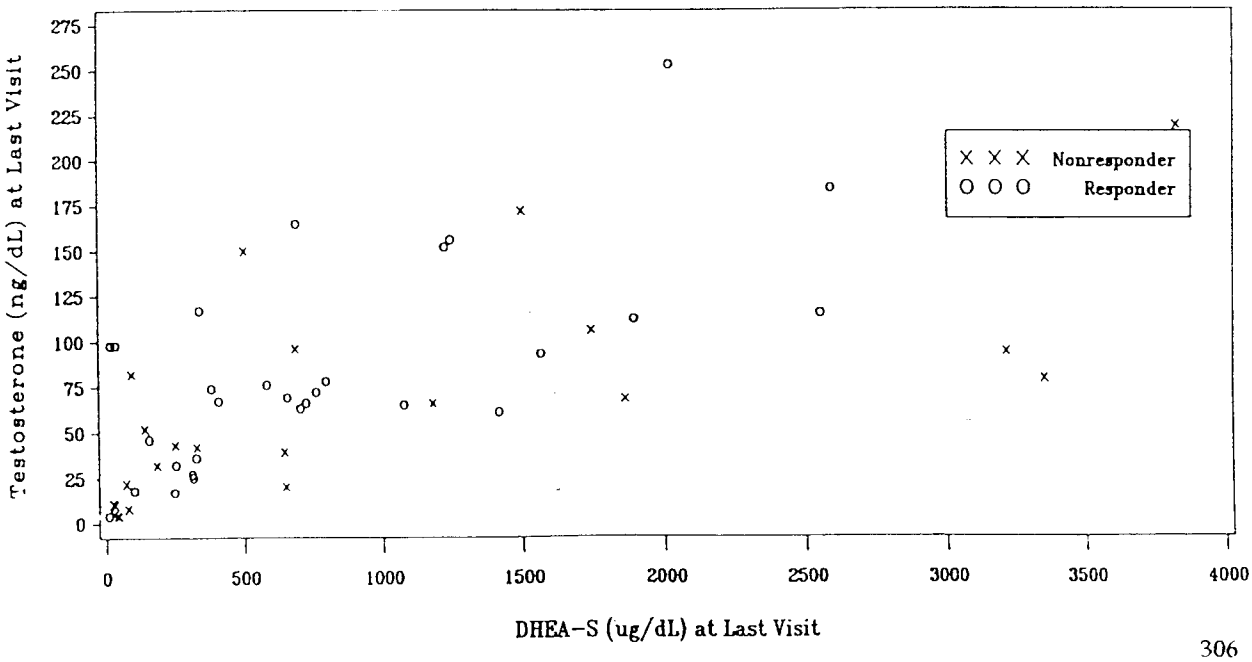


Figure 9.5.2.5-18: Testosterone vs. DHEA-S by Responder at Last Visit
(GL701 200mg Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-19: HDL vs. DHEA-S by Responder at Baseline
(Placebo Patients)

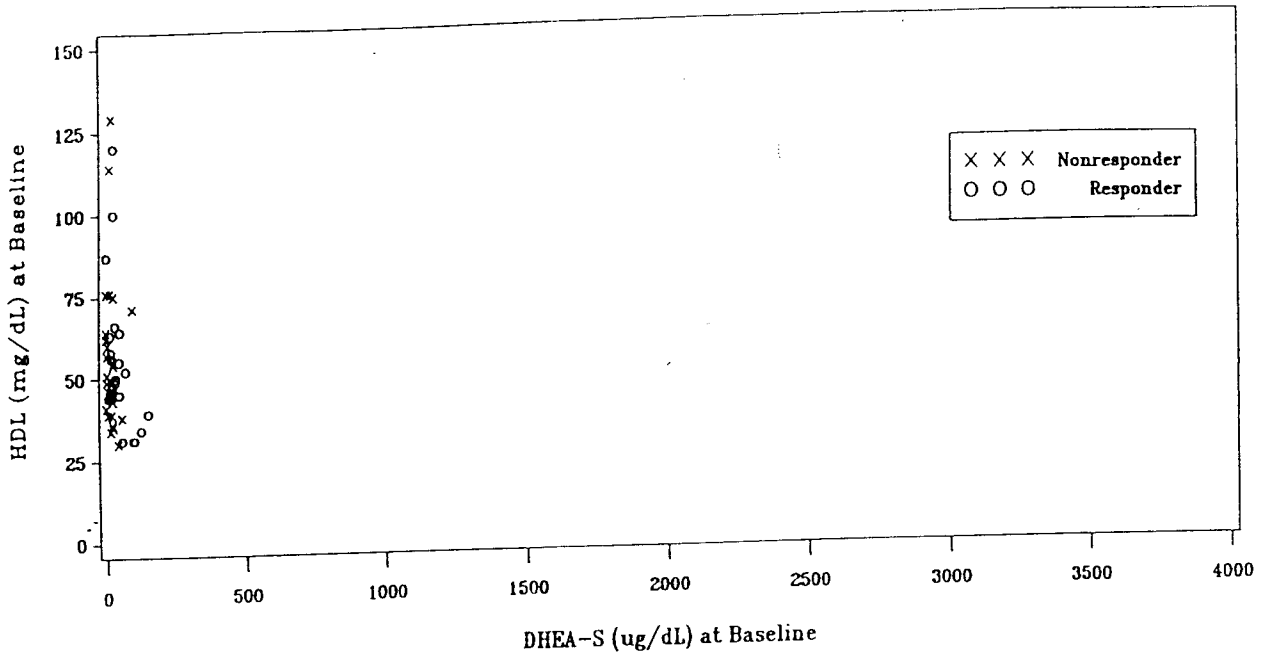
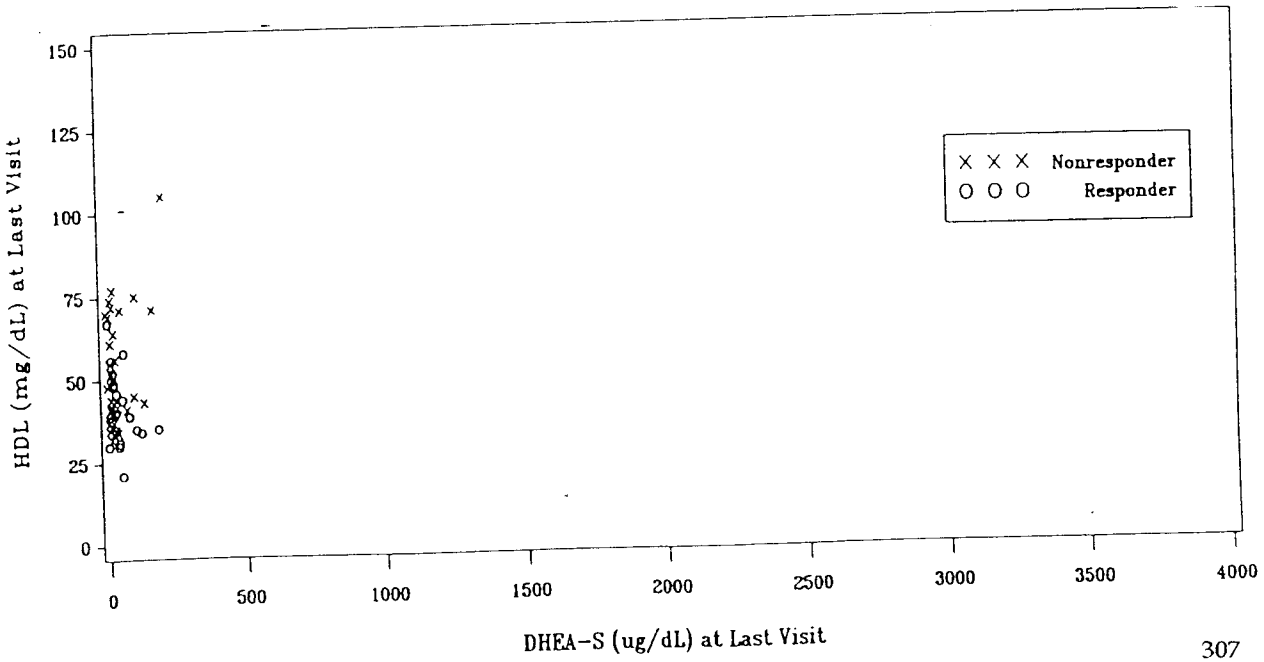


Figure 9.5.2.5-20: HDL vs. DHEA-S by Responder at Last Visit
(Placebo Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-21: HDL vs. DHEA-S by Responder at Baseline
(GL701 100mg Patients)

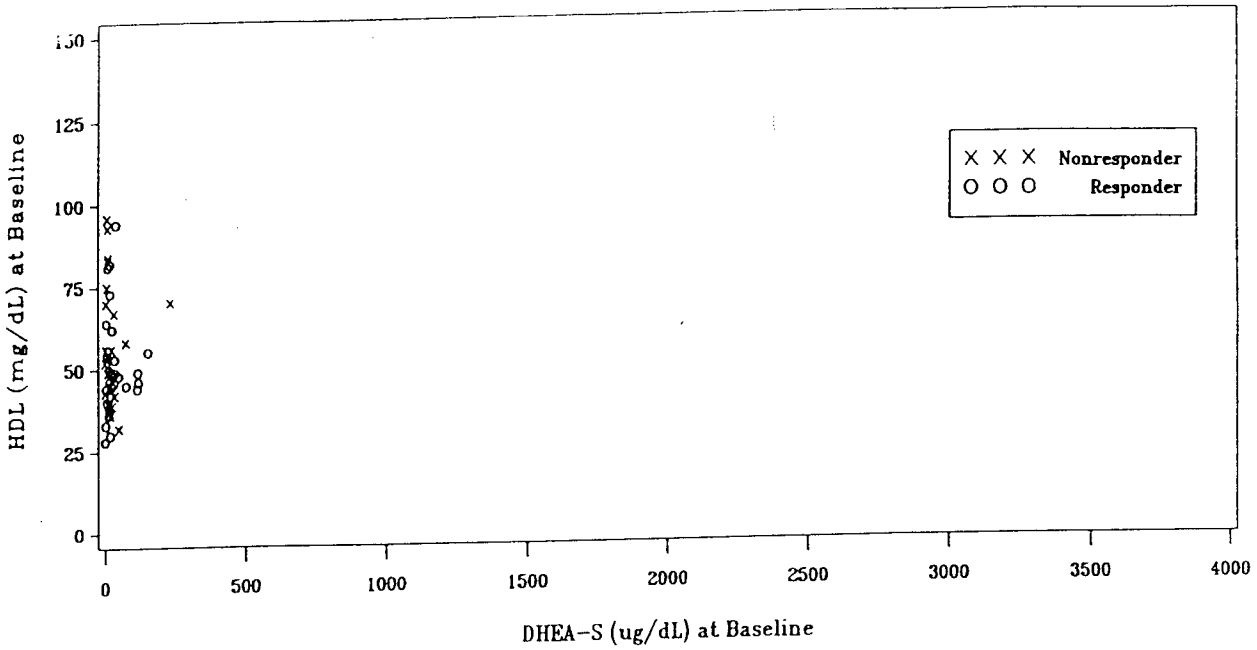
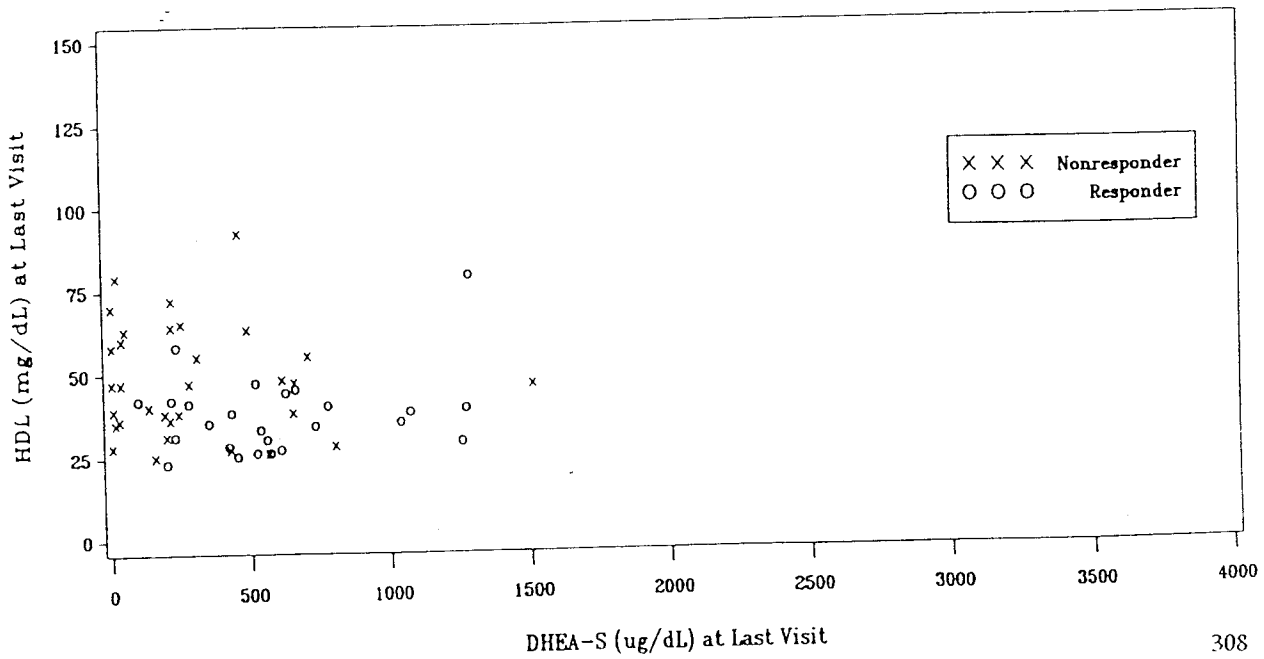


Figure 9.5.2.5-22: HDL vs. DHEA-S by Responder at Last Visit
(GL701 100mg Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

Figure 9.5.2.5-23: HDL vs. DHEA-S by Responder at Baseline
(GL701 200mg Patients)

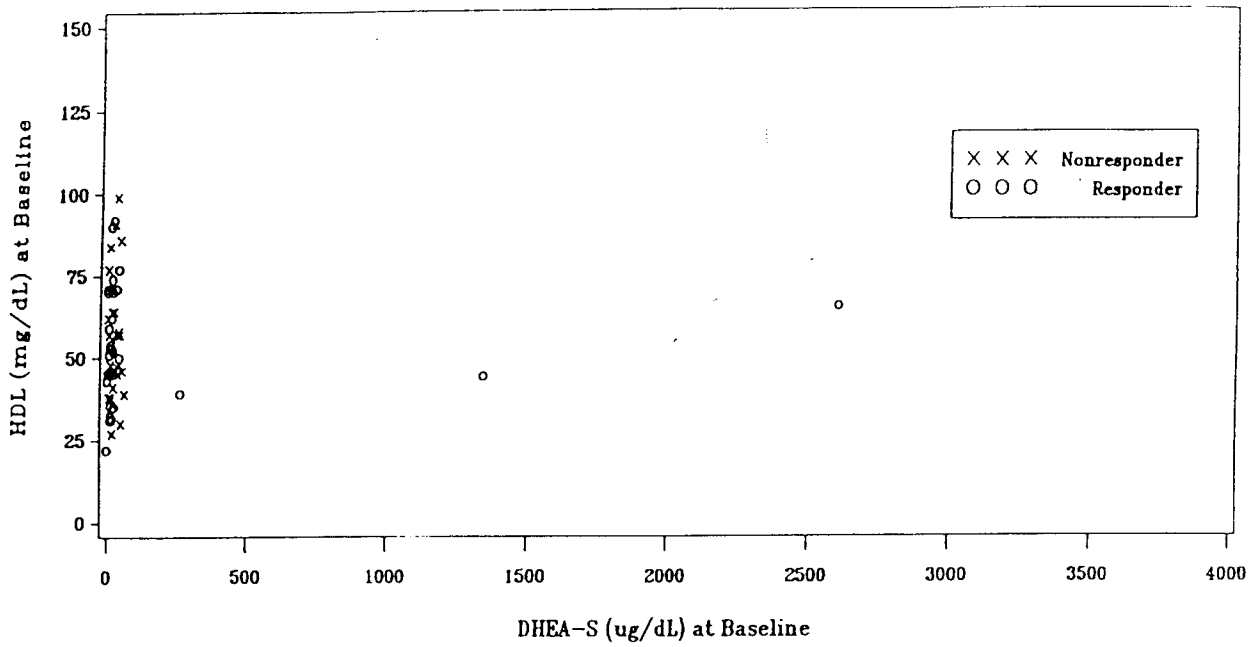
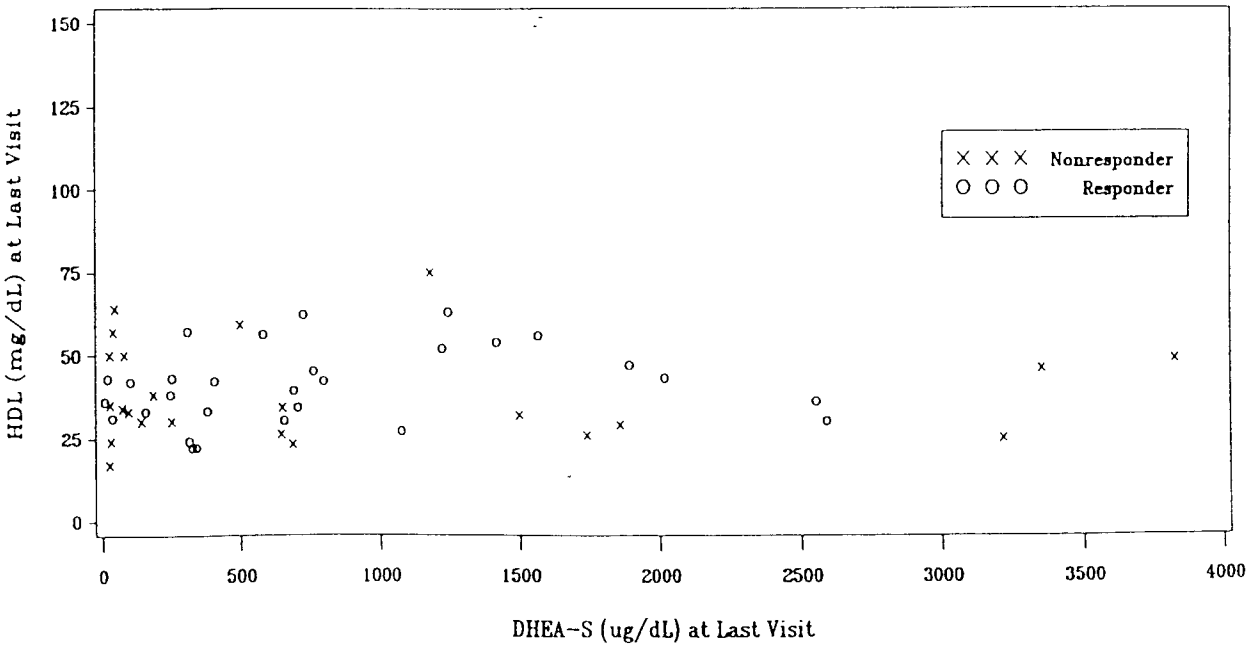


Figure 9.5.2.5-24: HDL vs. DHEA-S by Responder at Last Visit
(GL701 200mg Patients)



NOTE: Only patients who have a lab measurement within 2 days of last DHEA-S measurement appear in this plot.

TABLE 7

Frequency of Patients with Adverse Events by Treatment								
	Placebo (N=64)		GL701 100mg (N=63)			GL701 200mg (N=64)		
COSTART	N	(%)	N	(%)	P-value* 100 mg vs. Placebo	N	(%)	P-value* 200 mg vs. Placebo
Findings and Symptoms Which May Occur with SLE:								
ASTHENIA	19	(29.7)	23	(36.5)	0.4543	23	(35.9)	0.5725
ARTHRALGIA	24	(37.5)	15	(23.8)	0.1239	19	(29.7)	0.4543
RASH	15	(23.4)	14	(22.2)	1.0000	18	(28.1)	0.6865
HEADACHE	20	(31.3)	17	(27.0)	0.6969	17	(26.6)	0.6969
INFECT	21	(32.8)	17	(27.0)	0.5620	15	(23.4)	0.3257
FEVER	11	(17.2)	9	(14.3)	0.0979	14	(21.9)	0.6563
PAIN ABDO	4	(6.3)	7	(11.1)	0.3638	14	(21.9)	0.0201
MYALGIA	10	(15.6)	14	(22.2)	0.3728	13	(20.3)	0.6459
ARTHRITIS	16	(25.0)	17	(27.0)	0.8416	12	(18.8)	0.5218
NAUSEA	6	(9.4)	9	(14.3)	0.4235	10	(15.6)	0.4235
STOMATITIS ULCER	6	(9.4)	15	(23.8)	0.0333	10	(15.6)	0.4235
PAIN CHEST	7	(10.9)	5	(7.9)	0.7631	8	(12.5)	1.0000
HYPERTENS	1	(1.6)	2	(3.2)	0.6190	8	(12.5)	0.0326
EDEMA PERIPH	8	(12.5)	6	(9.5)	0.7781	8	(12.5)	1.0000
BRONCHITIS	6	(9.4)	5	(7.9)	1.0000	8	(12.5)	0.7781
DEPRESSION	3	(4.7)	5	(7.9)	0.4917	7	(10.9)	0.3237
ALOPECIA	9	(14.1)	7	(11.1)	0.7901	7	(10.9)	0.7901
SINUSITIS	13	(20.3)	4	(6.3)	0.0348	5	(7.8)	0.0729
RASHLE	13	(20.3)	9	(14.3)	0.4828	4	(6.3)	0.0348
Other Findings and Symptoms:								
ACNE	12	(18.8)	28	(44.4)	0.0022	28	(43.8)	0.0039
PAIN BACK	10	(15.6)	9	(14.3)	1.0000	9	(14.1)	1.0000
EDEMA PERIPH	8	(12.5)	6	(9.5)	0.7781	8	(12.5)	1.0000
METRO-RRHAGIA	5	(7.8)	6	(9.5)	0.7631	8	(12.5)	0.5600
PAIN	7	(10.9)	3	(4.8)	0.3237	7	(10.9)	1.0000
INFECT URIN TRACT	11	(17.2)	6	(9.5)	0.2975	5	(7.8)	0.1802
INSOMNIA	8	(12.5)	5	(7.9)	0.5600	5	(7.8)	0.5600
HIRSUTISM	3	(4.7)	7	(11.1)	0.2058	5	(7.8)	0.7176
COUGH INC	5	(7.8)	10	(15.9)	0.1802	5	(7.8)	1.0000

*P-values are obtained from Fisher's Exact Test using StatXact.

Source: Tables 9.2.2-1 (Table 10) and in Tables 9.2.2-2 - 9.2.2-4 (Volume II)

TABLE 8

Frequency of Patients With Severe Adverse Events
By Body System and COSTART

TREATMENT GROUP: DHEA 200mg					
BODY SYSTEM: Body as a Whole	Total	**BODY SYSTEM: Hematologic and Lymphatic**	Total		Total
COSTART n (%)		COSTART n (%)		**BODY SYSTEM: Dermatological**	
ASTHENIA	7 (11)	ANEMIA HYPOCHROM	1 (1.6)	PRURITUS	1 (1.6)
CELLULITIS	1 (1.6)	PROTHROMBIN DEC	1 (1.6)	RASH	2 (3.1)
FEVER	1 (1.6)	PURPURA	1 (1.6)	RASH LE	1 (1.6)
HEADACHE	4 (6.3)	THROMBOCYTOPENIA	1 (1.6)	URTICARIA	1 (1.6)
HERNIA	1 (1.6)	**BODY SYSTEM: Metabolic and Nutritional**		**BODY SYSTEM: Urogenital**	
INFECT	2 (3.1)	SGPT INC	1 (1.6)	DYSMENORRHEA	1 (1.6)
PAIN	1 (1.6)	**BODY SYSTEM: Musculoskeletal**			
PAIN ABDO	3 (4.7)	ARTHRALGIA	2 (3.1)		
PAIN CHEST SUBSTERN	1 (1.6)	ARTHRITIS	1 (1.6)		
BODY SYSTEM: Cardiovascular		ARTHROSIS	1 (1.6)		
HEART FAIL RIGHT	1 (1.6)	MYALGIA	1 (1.6)		
HYPERTENS	1 (1.6)	NECRO BONE			
TACHYCARDIA	1 (1.6)	PAIN BONE	1 (1.6)		
VASCULITIS	1 (1.6)	**BODY SYSTEM: Respiratory**	1 (1.6)		
BODY SYSTEM: Digestion		DYSPNEA	3 (4.7)		
STOMATITIS ULCER	1 (1.6)	NASAL SEPTUM DIS	1 (1.6)		
ULCER STOMACH	1 (1.6)	PLEURAL DIS	1 (1.6)		
ULCER STOMACH HEM	1 (1.6)	PNEUMONIA	1 (1.6)		
		PNEUMONIA INTERSTIT	1 (1.6)		

Frequency of Patients With Severe Adverse Events
By Body System and COSTART

TREATMENT GROUP: DHEA 100mg			
BODY SYSTEM: Body as a Whole	Total	**BODY SYSTEM: Musculoskeletal**	Total
COSTART n (%)		COSTART n (%)	
ASTHENIA	4 (6.3)	ARTHRALGIA	3 (4.8)
HEADACHE	1 (1.6)	ARTHRITIS	3 (4.8)
INFECT	3 (4.8)	MYALGIA	1 (1.6)
LE SYND	1 (1.6)	TENDON RUPT	1 (1.6)
PAIN ABDO	2 (3.2)	**BODY SYSTEM: Nervous System**	
PAIN BACK	2 (3.2)	DEPRESSION	1 (1.6)
PAIN CHEST	1 (1.6)	NERVOUSNESS	1 (1.6)
BODY SYSTEM: Cardiovascular		**BODY SYSTEM: Respiratory**	
HEM	1 (1.6)	COUGH INC	1 (1.6)
VASCULITIS	1 (1.6)	**BODY SYSTEM: Dermatological**	
BODY SYSTEM: Digestion		ALOPECIA	1 (1.6)
ABSCESS PERIODONT	1 (1.6)	ANGIOEDEMA	1 (1.6)
DIARRHEA	2 (3.2)	HIRSUTISM	1 (1.6)
NAUSEA	1 (1.6)	RASH	1 (1.6)
NAUSEA VOMIT	1 (1.6)	RASH LE	3 (4.8)
BODY SYSTEM: Hematologic and Lymphatic		SWEAT	1 (1.6)
ANEMIA	1 (1.6)	ULCER SKIN	2 (3.2)
ANEMIA HYPOCHROM	1 (1.6)	**BODY SYSTEM: Special Senses**	
BODY SYSTEM: Metabolic and Nutritional		OITIS EXT	1 (1.6)
CREATININE INC	1 (1.6)	**BODY SYSTEM: Urogenital**	
DEHYDRAT	1 (1.6)	ALBUMINURIA	1 (1.6)
EDEMA PERIPH	2 (3.2)	INFECT URIN TRACT	2 (3.2)
HYPOKALEM	1 (1.6)	KIDNEY CALCULUS	2 (3.2)
HYPOMAGNESEM	1 (1.6)		

Frequency of Patients With Severe Adverse Events
By Body System and COSTART

TREATMENT GROUP: PLACEBO			
BODY SYSTEM: Body as a Whole	Total	**BODY SYSTEM: Metabolic and Nutritional**	Total
COSTART n (%)		COSTART n (%)	
ASTHENIA	4 (6.3)	DEHYDRAT	1 (1.6)
CELLULITIS	1 (1.6)	EDEMA PERIPH	2 (3.1)
HEADACHE	8 (13)	**BODY SYSTEM: Musculoskeletal**	
OVERDOSE	1 (1.6)	ARTHRALGIA	4 (6.3)
PAIN CHEST	2 (3.1)	ARTHRITIS PYOGEN	1 (1.6)
SEPSIS	1 (1.6)	JOINT DIS	1 (1.6)
BODY SYSTEM: Cardiovascular		NECRO BONE	1 (1.6)
MIGRAINE	1 (1.6)	**BODY SYSTEM: Nervous System**	
VASC DIS PERIPH	1 (1.6)	DEPRESSION	1 (1.6)
BODY SYSTEM: Digestion		MYELITIS	1 (1.6)
DIARRHEA	1 (1.6)	PARESTHESIA	1 (1.6)
GI DIS	1 (1.6)	THINKING ABNORM	1 (1.6)
NAUSEA	1 (1.6)	**BODY SYSTEM: Respiratory**	
NAUSEA VOMIT	1 (1.6)	COUGH INC	1 (1.6)
ULCER ESOPH	1 (1.6)	DYSPNEA	1 (1.6)
ULCER MOUTH	1 (1.6)	PNEUMONIA	1 (1.6)
BODY SYSTEM: Digestion		**BODY SYSTEM: Dermatological**	
VOMIT	1 (1.6)	RASH	3 (4.7)
BODY SYSTEM: Hematologic and Lymphatic		**BODY SYSTEM: Urogenital**	
ANEMIA HEMOL	1 (1.6)	MENORRHAGIA	1 (1.6)
		NECRO KIDNEY TUBUL	1 (1.6)

TABLE 9

STUDY GL94-01
ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: BODY AS A WHOLE

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	14 (73.7)	13 (86.7)	10 (76.9)	13 (76.5)	11 (68.8)	14 (77.8)	12 (75.0)	12 (92.3)	14 (73.7)	9 (100.0)	18 (75.0)	9 (75.0)
COSTART												
ABDO ENLARGE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
ABSCESS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ADENOMA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
ALLERG REACT	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
ASCITES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
ASTHENIA	5 (26.3)	6 (40.0)	4 (30.8)	4 (23.5)	5 (31.3)	8 (44.4)	3 (18.8)	7 (53.8)	9 (47.4)	3 (33.3)	6 (25.0)	5 (41.7)
CELLULITIS	0 (0.0)	0 (0.0)	0 (0.0)	4 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (10.5)	1 (11.1)	0 (0.0)	1 (8.3)
CHILLS	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
CYST	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DRUG INTERACTION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EDEMA FACE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	1 (5.6)	1 (6.3)	1 (7.7)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
EDEMA GENERAL	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FEVER	3 (15.8)	1 (6.7)	2 (15.4)	5 (29.4)	1 (6.3)	3 (16.7)	2 (12.5)	3 (23.1)	6 (31.6)	1 (11.1)	3 (12.5)	4 (33.3)
FLU SYND	0 (0.0)	1 (6.7)	2 (15.4)	1 (5.9)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
HEADACHE	4 (21.1)	3 (20.0)	6 (46.2)	7 (41.2)	2 (12.5)	6 (33.3)	4 (25.0)	5 (38.5)	3 (15.8)	4 (44.4)	7 (29.2)	3 (25.0)
HERNIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
INFECT	9 (47.4)	5 (33.3)	3 (23.1)	4 (23.5)	4 (25.0)	3 (16.7)	7 (43.8)	3 (23.1)	5 (26.3)	2 (22.2)	5 (20.8)	3 (25.0)
INFECT FUNG	1 (5.3)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	2 (10.5)	1 (11.1)	1 (4.2)	0 (0.0)
INJURY ACCID	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	1 (11.1)	2 (8.3)	0 (0.0)
LE SYND	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	2 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MALAISE	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
MUCOUS MEM DIS	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEOPL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
OVERDOSE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PAIN	3 (15.8)	1 (6.7)	0 (0.0)	3 (17.6)	2 (12.5)	1 (5.6)	0 (0.0)	0 (0.0)	2 (10.5)	0 (0.0)	5 (20.8)	0 (0.0)
PAIN ABDO	2 (10.5)	0 (0.0)	2 (15.4)	0 (0.0)	1 (6.3)	3 (16.7)	1 (6.3)	2 (15.4)	3 (15.8)	2 (22.2)	7 (29.2)	2 (16.7)
PAIN BACK	2 (10.5)	1 (6.7)	3 (23.1)	4 (23.5)	3 (18.8)	4 (22.2)	1 (6.3)	1 (7.7)	4 (21.1)	1 (11.1)	3 (12.5)	1 (8.3)
PAIN CHEST	1 (5.3)	2 (13.3)	1 (7.7)	3 (17.6)	3 (18.8)	1 (5.6)	0 (0.0)	1 (7.7)	2 (10.5)	2 (22.2)	2 (8.3)	2 (16.7)
PAIN CHEST SUBSTERN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
PAIN NECK	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8.3)	0 (0.0)
PHOTOSENSITIVITY	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SEPSIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: BODY AS A WHOLE

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
COSTART												
UNEXPECTED BENEFIT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: CARDIOVASCULAR

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	5 (26.3)	6 (40.0)	5 (38.5)	7 (41.2)	6 (37.5)	5 (27.8)	4 (25.0)	4 (30.8)	6 (31.6)	2 (22.2)	7 (29.2)	6 (50.0)
COSTART												
ANGINA PECTORIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
ANOMALY HEART	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANOMALY VASCUL	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARDIOVASC DIS	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	2 (12.5)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
HEART FAIL LEFT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
HEART FAIL RIGHT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8.3)	0 (0.0)
HEM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPERTENS	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	1 (7.7)	2 (10.5)	1 (11.1)	3 (12.5)	2 (16.7)
HYPOTENS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
HYPOTENS POST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MIGRAINE	0 (0.0)	2 (13.3)	2 (15.4)	2 (11.8)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	1 (8.3)
PALPITAT	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	2 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
PERICARDITIS	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
STENO AORTIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
TACHYCARDIA	0 (0.0)	0 (0.0)	2 (15.4)	1 (5.9)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
THROMBOPHLEB	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THROMBOPHLEB DEEP	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VASC DIS	2 (10.5)	1 (6.7)	0 (0.0)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)	1 (7.7)	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)
VASC DIS PERIPH	3 (15.8)	1 (6.7)	1 (7.7)	0 (0.0)	0 (0.0)	2 (11.1)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
VASCULITIS	0 (0.0)	0 (0.0)	1 (7.7)	2 (11.8)	1 (6.3)	0 (0.0)	1 (6.3)	1 (7.7)	0 (0.0)	1 (11.1)	1 (4.2)	3 (25.0)
VASODILAT	1 (5.3)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
VASOSPASM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: DIGESTION

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	6 (31.6)	5 (33.3)	7 (53.8)	10 (58.8)	9 (56.3)	12 (66.7)	8 (50.0)	7 (53.8)	7 (36.8)	4 (44.4)	13 (54.2)	5 (41.7)
COSTART												
ABSCESS PERIODONT	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANOREXIA	0 (0.0)	1 (6.7)	1 (7.7)	3 (17.6)	1 (6.3)	2 (11.1)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
APPETITE INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
CARDIOSPASM	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CHOLECYST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CONSTIP	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
DIARRHEA	0 (0.0)	1 (6.7)	2 (15.4)	2 (11.8)	2 (12.5)	3 (16.7)	1 (6.3)	0 (0.0)	2 (10.5)	0 (0.0)	1 (4.2)	2 (16.7)
DRY MOUTH	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DYSPEPSIA	1 (5.3)	0 (0.0)	1 (7.7)	2 (11.8)	0 (0.0)	2 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
FLATUL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
GASTRITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
GASTROENTERITIS	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
GGTP INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
GI DIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
GLOSSITIS	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEPATOMEGALY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
JAUNDICE CHOLESTAT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
LIVER FUNC ABNORM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
MELENA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
MONILIA ORAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	1 (7.7)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
NAUSEA	2 (10.5)	0 (0.0)	3 (23.1)	1 (5.9)	1 (6.3)	5 (27.8)	1 (6.3)	2 (15.4)	1 (5.3)	1 (11.1)	6 (25.0)	2 (16.7)
NAUSEA VOMIT	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	1 (5.6)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
NEOPL LIVER	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OBSTRUCT INTEST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
STOMATITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
STOMATITIS APHTH	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	1 (11.1)	0 (0.0)	0 (0.0)
STOMATITIS ULCER	0 (0.0)	2 (13.3)	2 (15.4)	2 (11.8)	4 (25.0)	4 (22.2)	3 (18.8)	4 (30.8)	4 (21.1)	3 (33.3)	2 (8.3)	1 (8.3)
STOOL ABNORM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
THIRST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
TOOTH CARIES	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOOTH DIS	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ULCER ESOPH	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: r:\genelabs\dhea\fda\newreq\fda\12_21_2000\ae_sled.sas 6.12 19JAN01

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: DIGESTION

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
COSTART												
ULCER MOUTH	2 (10.5)	0 (0.0)	1 (7.7)	1 (5.9)	3 (18.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	1 (11.1)	1 (4.2)	0 (0.0)
ULCER STOMACH	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
ULCER STOMACH HEM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
VOMIT	2 (10.5)	0 (0.0)	1 (7.7)	1 (5.9)	1 (6.3)	1 (5.6)	0 (0.0)	1 (7.7)	0 (0.0)	1 (11.1)	3 (12.5)	0 (0.0)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: ENDOCRINE

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (15.4)	0 (0.0)	0 (0.0)	1 (4.2)	2 (16.7)
COSTART												
CUSHINGS SYND	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
GOITER	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: HEMATOLOGIC AND LYMPHATIC

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	2 (10.5)	2 (13.3)	3 (23.1)	6 (35.3)	3 (18.8)	3 (16.7)	2 (12.5)	5 (38.5)	3 (15.8)	1 (11.1)	2 (8.3)	4 (33.3)
COSTART												
ANEMIA	0 (0.0)	1 (6.7)	0 (0.0)	1 (5.9)	0 (0.0)	1 (5.6)	0 (0.0)	3 (23.1)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
ANEMIA HEMOL	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANEMIA HYPOCHROM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
BLEED TIME INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ECCHYMOSIS	1 (5.3)	0 (0.0)	1 (7.7)	1 (5.9)	1 (6.3)	1 (5.6)	0 (0.0)	3 (23.1)	0 (0.0)	1 (11.1)	0 (0.0)	1 (8.3)
LEUKOCYTE VACUOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LEUKOCYTOSIS	0 (0.0)	1 (6.7)	0 (0.0)	1 (5.9)	1 (6.3)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
LEUKOPENIA	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (6.3)	1 (7.7)	1 (5.3)	0 (0.0)	1 (4.2)	1 (8.3)
LYMPHADENO	1 (5.3)	0 (0.0)	2 (15.4)	2 (11.8)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
MEGAKARYO INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
PETECHIA	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROTHROMBIN DEC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
PURPURA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
THROMBOCYTHEM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THROMBOCYTOPENIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: METABOLIC AND NUTRITIONAL

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	4 (21.1)	3 (20.0)	7 (53.8)	3 (17.6)	2 (12.5)	3 (16.7)	3 (18.8)	6 (46.2)	3 (15.8)	1 (11.1)	3 (12.5)	4 (33.3)
COSTART												
ALBUMINURIA	1 (5.3)	0 (0.0)	1 (7.7)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CREATINE PK INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CREATININE INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
DEHYDRAT	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
EDEMA	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
EDEMA GENERAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
EDEMA PERIPH	3 (15.8)	1 (6.7)	4 (30.8)	0 (0.0)	0 (0.0)	2 (11.1)	0 (0.0)	4 (30.8)	1 (5.3)	1 (11.1)	2 (8.3)	4 (33.3)
GOUT	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPERGLYCEM	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPOKALEM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPOMAGNESEM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPOPROTEINEM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
PHOSPHATASE ALK INC	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SGOT INC	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	1 (6.3)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
SGPT INC	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.6)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8.3)	0 (0.0)
WEIGHT DEC	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
WEIGHT INC	0 (0.0)	1 (6.7)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: MUSCULOSKELETAL

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	14 (73.7)	9 (60.0)	6 (46.2)	11 (64.7)	10 (62.5)	12 (66.7)	12 (75.0)	6 (46.2)	13 (68.4)	6 (66.7)	16 (66.7)	7 (58.3)
COSTART												
ARTHRALGIA	8 (42.1)	5 (33.3)	4 (30.8)	7 (41.2)	5 (31.3)	6 (33.3)	2 (12.5)	2 (15.4)	5 (26.3)	3 (33.3)	8 (33.3)	3 (25.0)
ARTHRITIS	4 (21.1)	3 (20.0)	3 (23.1)	6 (35.3)	3 (18.8)	6 (33.3)	7 (43.8)	1 (7.7)	3 (15.8)	1 (11.1)	5 (20.8)	3 (25.0)
ARTHRITIS PYOGEN	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ARTHRITIS RHEUMAT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)
ARTHROSIS	0 (0.0)	2 (13.3)	2 (15.4)	1 (5.9)	1 (6.3)	2 (11.1)	1 (6.3)	0 (0.0)	1 (5.3)	0 (0.0)	1 (4.2)	1 (8.3)
BONE FRACT SPONTAN	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BURSITIS	1 (5.3)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CRAMPS LEG	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
JOINT DIS	3 (15.8)	1 (6.7)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
MYALGIA	3 (15.8)	3 (20.0)	2 (15.4)	2 (11.8)	3 (18.8)	4 (22.2)	4 (25.0)	3 (23.1)	4 (21.1)	2 (22.2)	4 (16.7)	3 (25.0)
MYASTHENIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	1 (5.6)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	2 (8.3)	0 (0.0)
MYOSITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
NECRO BONE	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)
PAIN BONE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)
SPASM GENERAL	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
SYNOVITIS	1 (5.3)	1 (6.7)	2 (15.4)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	2 (10.5)	0 (0.0)	0 (0.0)	1 (8.3)
TENDON DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	1 (6.3)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
TENDON RUPT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TENOSYNOVITIS	1 (5.3)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: NERVOUS SYSTEM

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	6 (31.6)	3 (20.0)	8 (61.5)	8 (47.1)	2 (12.5)	7 (38.9)	3 (18.8)	8 (61.5)	5 (26.3)	2 (22.2)	11 (45.8)	5 (41.7)
COSTART												
AGITATION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
AMNESIA	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANXIETY	0 (0.0)	1 (6.7)	1 (7.7)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	2 (8.3)	0 (0.0)
BRAIN SYND ACUTE	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
DEPRESSION	0 (0.0)	0 (0.0)	2 (15.4)	1 (5.9)	0 (0.0)	3 (16.7)	0 (0.0)	2 (15.4)	1 (5.3)	2 (22.2)	2 (8.3)	2 (16.7)
DEPRESSION PSYCHOTIC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
DIZZINESS	1 (5.3)	1 (6.7)	0 (0.0)	2 (11.8)	0 (0.0)	3 (16.7)	0 (0.0)	2 (15.4)	2 (10.5)	0 (0.0)	1 (4.2)	0 (0.0)
EMOTION LABIL	0 (0.0)	0 (0.0)	3 (23.1)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.3)	0 (0.0)	1 (4.2)	1 (8.3)
HALLUCIN	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HOSTILITY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
HYPERTONIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
HYPESTHESIA	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (6.3)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPOKINESIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
INSOMNIA	2 (10.5)	0 (0.0)	2 (15.4)	4 (23.5)	0 (0.0)	1 (5.6)	2 (12.5)	2 (15.4)	0 (0.0)	0 (0.0)	2 (8.3)	3 (25.0)
LIBIDO INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	2 (16.7)
MYELITIS	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MYOCLONUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NERVOUSNESS	1 (5.3)	0 (0.0)	1 (7.7)	1 (5.9)	0 (0.0)	2 (11.1)	1 (6.3)	1 (7.7)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
NEURALGIA	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (4.2)	1 (8.3)
NEUROPATHY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
PARESTHESIA	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8.3)	0 (0.0)
SOMNOLENCE	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	2 (8.3)	0 (0.0)
THINKING ABNORM	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
TREMOR	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.1)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	1 (8.3)
VERTIGO	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: RESPIRATORY

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	10 (52.6)	10 (66.7)	5 (38.5)	10 (58.8)	9 (56.3)	6 (33.3)	4 (25.0)	6 (46.2)	4 (21.1)	4 (44.4)	12 (50.0)	7 (58.3)
COSTART												
ASTHMA	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
BRONCHITIS	3 (15.8)	2 (13.3)	0 (0.0)	1 (5.9)	3 (18.8)	0 (0.0)	1 (6.3)	1 (7.7)	0 (0.0)	1 (11.1)	4 (16.7)	3 (25.0)
COUGH INC	2 (10.5)	0 (0.0)	1 (7.7)	2 (11.8)	2 (12.5)	3 (16.7)	2 (12.5)	3 (23.1)	1 (5.3)	0 (0.0)	2 (8.3)	2 (16.7)
DYSPNEA	0 (0.0)	3 (20.0)	1 (7.7)	2 (11.8)	1 (6.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (4.2)	1 (8.3)
EPISTAXIS	1 (5.3)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	2 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
HEMOPTYSIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
LUNG DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NASAL SEPTUM DIS	0 (0.0)	1 (6.7)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (15.4)	0 (0.0)	0 (0.0)	2 (8.3)	0 (0.0)
PHARYNGITIS	1 (5.3)	0 (0.0)	1 (7.7)	3 (17.6)	2 (12.5)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PLEURAL DIS	1 (5.3)	3 (20.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	2 (10.5)	2 (22.2)	1 (4.2)	1 (8.3)
PNEUMONIA	0 (0.0)	2 (13.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
PNEUMONIA INTERSTIT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
RESPIRAT DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
RHINITIS	1 (5.3)	0 (0.0)	0 (0.0)	2 (11.8)	1 (6.3)	1 (5.6)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8.3)	1 (8.3)
SINUSITIS	3 (15.8)	3 (20.0)	1 (7.7)	6 (35.3)	2 (12.5)	0 (0.0)	1 (6.3)	1 (7.7)	0 (0.0)	1 (11.1)	2 (8.3)	2 (16.7)
VOICE ALTERAT	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: DERMATOLOGICAL

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	12 (63.2)	11 (73.3)	10 (76.9)	13 (76.5)	11 (68.8)	16 (88.9)	12 (75.0)	12 (92.3)	12 (63.2)	7 (77.8)	18 (75.0)	9 (75.0)
COSTART												
ACNE	5 (26.3)	4 (26.7)	2 (15.4)	1 (5.9)	7 (43.8)	11 (61.1)	6 (37.5)	4 (30.8)	12 (63.2)	1 (11.1)	10 (41.7)	5 (41.7)
ALOPECIA	0 (0.0)	4 (26.7)	3 (23.1)	2 (11.8)	1 (6.3)	2 (11.1)	1 (6.3)	3 (23.1)	1 (5.3)	2 (22.2)	1 (4.2)	3 (25.0)
ANGIOEDEMA	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DERM CONTACT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DERM EXFOL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
ECZEMA	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HERPES SIMPLEX	0 (0.0)	1 (6.7)	2 (15.4)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
HERPES ZOSTER	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
HIRSUTISM	2 (10.5)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (16.7)	0 (0.0)	4 (30.8)	2 (10.5)	0 (0.0)	2 (8.3)	1 (8.3)
HYPERTROPHY SKIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NAIL DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (7.7)	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)
NECRO SKIN	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEOPL SKIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
NODULE SKIN	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.9)	2 (12.5)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NODULE SUBCUTAN	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PRURITUS	2 (10.5)	0 (0.0)	0 (0.0)	1 (5.9)	1 (6.3)	2 (11.1)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (12.5)	1 (8.3)
PSORIASIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RASH	2 (10.5)	3 (20.0)	3 (23.1)	7 (41.2)	4 (25.0)	4 (22.2)	3 (18.8)	3 (23.1)	3 (15.8)	4 (44.4)	8 (33.3)	3 (25.0)
RASH LE	4 (21.1)	1 (6.7)	3 (23.1)	5 (29.4)	3 (18.8)	1 (5.6)	2 (12.5)	3 (23.1)	3 (15.8)	0 (0.0)	1 (4.2)	0 (0.0)
RASH MAC PAP	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.9)	1 (6.3)	1 (5.6)	1 (6.3)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
RASH PUST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RASH VESIC BULL	0 (0.0)	1 (6.7)	2 (15.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (4.2)	0 (0.0)
SEBORRHEA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
SKIN DIS	1 (5.3)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	1 (11.1)	1 (4.2)	0 (0.0)
SKIN DISCOLOR	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	1 (6.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
SKIN DRY	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
SWEAT	1 (5.3)	1 (6.7)	0 (0.0)	1 (5.9)	1 (6.3)	2 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
ULCER SKIN	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	1 (7.7)	0 (0.0)	1 (11.1)	0 (0.0)	1 (8.3)
URTICARIA	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)

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STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: SPECIAL SENSES

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	3 (15.8)	2 (13.3)	2 (15.4)	3 (17.6)	2 (12.5)	5 (27.8)	5 (31.3)	2 (15.4)	1 (5.3)	0 (0.0)	3 (12.5)	3 (25.0)
COSTART												
AMBLYOPIA	1 (5.3)	1 (6.7)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	1 (8.3)
CATARACT	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CONJUNCTIVITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	1 (5.6)	2 (12.5)	1 (7.7)	1 (5.3)	0 (0.0)	1 (4.2)	1 (8.3)
DRY EYE	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EAR DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEM EYE	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OTITIS EXT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
OTITIS MED	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.9)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
PAIN EAR	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SCLERITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TASTE PERVERS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TINNITUS	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
UVEITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VISION ABNORM	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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STUDY GL94-01

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: UROGENITAL

	Placebo				100 mg				200 mg			
Baseline SLEDAI	0-2 (N= 19)	>2-4 (N= 15)	>4-8 (N= 13)	>8 (N= 17)	0-2 (N= 16)	>2-4 (N= 18)	>4-8 (N= 16)	>8 (N= 13)	0-2 (N= 19)	>2-4 (N= 9)	>4-8 (N= 24)	>8 (N= 12)
Body System Total	6 (31.6)	5 (33.3)	8 (61.5)	7 (41.2)	6 (37.5)	5 (27.8)	7 (43.8)	7 (53.8)	10 (52.6)	2 (22.2)	8 (33.3)	5 (41.7)
COSTART												
ABORTION	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALBUMINURIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	2 (12.5)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
AMENORRHEA	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CYSTITIS	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)
DYSMENORRHEA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
DYSURIA	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ENDOMETR DIS	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEM VAGINAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
HEMATURIA	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.3)	0 (0.0)	1 (4.2)	0 (0.0)
INCONTIN URIN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
INFECT URIN TRACT	2 (10.5)	3 (20.0)	4 (30.8)	2 (11.8)	0 (0.0)	1 (5.6)	4 (25.0)	1 (7.7)	1 (5.3)	0 (0.0)	2 (8.3)	2 (16.7)
KIDNEY CALCULUS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
KIDNEY FUNC ABNORM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
LEUKORRHEA	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)
MENORRHAGIA	1 (5.3)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
MENS DIS	1 (5.3)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
METRORRHAGIA	1 (5.3)	1 (6.7)	2 (15.4)	1 (5.9)	2 (12.5)	2 (11.1)	0 (0.0)	2 (15.4)	4 (21.1)	1 (11.1)	1 (4.2)	2 (16.7)
MONILIA VAGINA	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)	1 (6.3)	0 (0.0)	1 (6.3)	2 (15.4)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)
NECRO KIDNEY TUBUL	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEPHRITIS	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
NEPHROSIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PYURIA	0 (0.0)	0 (0.0)	0 (0.0)	3 (17.6)	2 (12.5)	0 (0.0)	0 (0.0)	2 (15.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SALPINGITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
URIN ABNORM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
URIN FREQUENCY	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
URIN IMPAIRED	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
VAGINITIS	0 (0.0)	1 (6.7)	1 (7.7)	1 (5.9)	0 (0.0)	0 (0.0)	1 (6.3)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)

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ABLE 10

Abdominal Pain AEs Mapped to COSTART Term "PAIN ABDO" in Study GL94-01

ID	TREAT-MENT	AE Verbatim Term	COSTART	AE Related to Study Drug?*	AE Related to SLE?*	AE Onset Date	AE Resolu-tion Date	Req. Other Med.	AE Outcome	AE Severity
28242	Placebo	LLQ ABDOMINAL PAINS	PAIN ABDO	not rel	not rel	2/21/95	4/1/95	no	recovered	mod
14271	Placebo	INTESTINAL SPASMS	PAIN ABDO	not rel	not rel	5/25/95	6/15/95	yes	recovered	mod
3150	Placebo	EPIGASTRIC PAIN WHEN TAKING NAPROSYN	PAIN ABDO	not rel	not rel	6/10/95		yes	under Rx	mild
20158	Placebo	EPIGASTRIC PAIN	PAIN ABDO	not rel	not rel	11/1/94	1/10/95	no	recovered	mild
21202	Placebo	RLQ TENDERNESS	PAIN ABDO	unknown	possibly	12/11/95		no	alive w sequ	mild
27208	Placebo	(R) UPPER QUADRANT PAIN R/T INCREASED REFLUX ESOPHAGITIS	PAIN ABDO	unknown	unknown	9/14/95	10/11/95	yes	recovered	mild
28244	100 mg	STOMACH CRAMPS	PAIN ABDO	not rel	not rel	6/1/95	6/12/95	yes	recovered	severe
28244	100 mg	STOMACH CRAMP	PAIN ABDO	not rel	not rel	4/8/95	4/11/95	no	recovered	severe
14230	100 mg	PEPTIC DISTRESS	PAIN ABDO	not rel	not rel	10/--/95		yes	under Rx	mild
20224	100 mg	INTERMITTENT STOMACH PAIN	PAIN ABDO	not rel	not rel	6/1/95		yes	under Rx	mod
14231	100 mg	ABDOMINAL WALL TENDERNESS	PAIN ABDO	not rel	not rel	4/1/95	4/15/95	no	recovered	mild
20157	100 mg	ABDOMINAL PAIN	PAIN ABDO	not rel	not rel	01/--/95	02/--/95	no	recovered	mod
17330	100 mg	ABD PAIN	PAIN ABDO	not rel	not rel	8/10/95	10/--/95	no	recovered	mild
30268	100 mg	(R) LOWER ABDOMINAL PAIN	PAIN ABDO	not rel	not rel	6/26/95	6/26/95	no	recovered	severe
15166	100 mg	TENDER ABDOMEN	PAIN ABDO	possibly	probably	1/23/95	2/24/95	no	recovered	mod
12116	100 mg	ABDOMINAL PAIN (EPIGASTRIC DISCOMFORT)	PAIN ABDO	possibly	possibly	9/12/94		yes	under Rx	mild
13105	100 mg	ABD. CRAMPS WITH DIARRHEA	PAIN ABDO	possibly	possibly	11/4/94	11/11/94	no	recovered	mod
3152	200 mg	ABDOMEN - TENDER LUQ	PAIN ABDO	not rel	possibly	4/20/95		no	under Rx	mild
3152	200 mg	UPPER GI PAIN	PAIN ABDO	not rel	not rel	9/22/95		yes	under Rx	mild
3152	200 mg	TENDERNESS R LOWER QUADRANT IN ABDOMEN	PAIN ABDO	not rel	not rel	9/10/95		yes	under Rx	mod
3152	200 mg	TENDER L LOWER QUADRANT IN ABDOMEN	PAIN ABDO	not rel	not rel	9/10/95		yes	under Rx	mod
14227	200 mg	STOMACH PAIN	PAIN ABDO	not rel	not rel	042895		yes	alive w sequ	mod
16195	200 mg	SLIGHT (R) UPPER QUADRANT TENDERNESS	PAIN ABDO	not rel	not rel	10/20/95		no	under Rx	mild
17178	200 mg	MILD TENDERNESS RLABD	PAIN ABDO	not rel	not rel	6/14/95	06/--/95	no	recovered	mild

Abdominal Pain AEs Mapped to COSTART Term "PAIN ABDO" in Study GL94-01

14227	200 mg	EPIGASTRIC PAIN	PAIN ABDO	not rel	not rel	11/4/94	11/13/94	yes	recovered	mild
19246	200 mg	EPIGASTRIC PAIN	PAIN ABDO	not rel	possibly	1/24/96		no	alive w sequ	mod
20221	200 mg	BURNING ABDOMINAL DISCOMFORT	PAIN ABDO	not rel	not rel	4/28/95	05/--/95	yes	recovered	mild
14227	200 mg	ABDOMINAL PAIN/SEROSITIS	PAIN ABDO	not rel	probably	11/14/94	11/18/94	no	recovered	severe
19248	200 mg	ABDOMINAL PAIN & DISCOMFORT	PAIN ABDO	not rel	not rel	9/15/95	9/19/95	no	recovered	mod
18130	200 mg	ABD SEROSITIS	PAIN ABDO	not rel	probably	8/31/95	9/14/95	no	recovered	mod
19246	200 mg	(L) SIDE ABDOMINAL PAIN	PAIN ABDO	not rel	possibly	11/8/95	1/31/96	no	recovered	mild
17173	200 mg	(L) LOWER ABD TENDERNESS	PAIN ABDO	not rel	probably	7/12/95	9/29/95	no	recovered	mild
12118	200 mg	RUQ AND LUQ PAIN (ABDOMINAL)	PAIN ABDO	possibly	possibly	5/12/95	5/17/95	no	recovered	mild
15163	200 mg	EPIGASTRIC PAIN PERSISTENT	PAIN ABDO	possibly	unknown	12/5/94	3/27/95	no	recovered	mod
12118	200 mg	ABDOMINAL PAIN (DULL ACHE IN RUQ)	PAIN ABDO	possibly	possibly	1/24/95	5/1/95	no	recovered	mild
14109	200 mg	ABDOMINAL PAIN	PAIN ABDO	possibly	unknown	10/18/94	10/26/94	no	recovered	mod
22172	200 mg	ABDOMINAL PAIN	PAIN ABDO	possibly	not rel	8/31/95	9/7/95	no	recovered	mild
12118	200 mg	ABDOMINAL CRAMPING	PAIN ABDO	possibly	not rel	12/3/94	12/3/94	no	recovered	mild
12119	200 mg	LOWER ABDOMINAL CRAMPING; DIARRHEA	PAIN ABDO	probably	not rel	2/7/95	2/10/95	yes	recovered	severe
12119	200 mg	ABDOMINAL PAIN (LOWER ABDOMINAL)	PAIN ABDO	probably	not rel	3/5/95	3/5/95	no	recovered	mod
15162	200 mg	PAIN IN (R) ABDOMEN STABBING IN CHARACTER NO FEVER NO DIAPHORESIS	PAIN ABDO	unknown	possibly	1/14/95	2/6/95	no	recovered	severe
21197	200 mg	GAS PAINS	PAIN ABDO	unknown	unknown	1/9/95	1/31/95	no	recovered	mod

* As Assessed by the Investigator

TABLE 11

Estradiol (pg/ml) in Pre-menopausal SLE Patients (Study GL94-01) Excluding patients Who Received Exogenous Estrogens or Progestins				
Treatment Group		**Baseline[1]**	**Last Visit[2]**	**Change from Baseline to Last Visit**
Placebo	No.	34	32	32
	Mean (SD)	95.2 (75.7)	97.0 (70.6)	0.8 (91.0)
	Median	78.2	80.0	-[illegible].4
	Range	1.4*/378.9	1.4*/287.6	-132.5/225.1
GL701 100mg/day	No.	35	34	34
	Mean (SD)	106.9 (84.5)	101.0 (77.0)	-3.9 (73.7)
	Median	87.1	105.8	4.0
	Range	1.4*/386.9	1.4*/364.4	-168.7/106.3
GL701 200 mg/day	No.	45	41	40
	Mean (SD)	105.6 (91.3)	115.1 (127.3)	16.2 (167.7)
	Median	85.6	76.3	17.1
	Range	1.4*/338.0	1.4*/735.3	-316.4/688.2

[1] Baseline refers to the last pre-dose measurement.

[2] Last Visit refers to the last post-baseline measurement in the core study. *Minimum measurable quantity.

Source: Tables 11.3.6.1 and 11.3.6.2 (Volume III)

Estradiol (pg/ml) in Post-menopausal SLE Patients (Study GL94-01) Excluding patients Who Received Exogenous Estrogens or Progestins				
Treatment Group		**Baseline[1]**	**Last Visit[2]**	**Change from Baseline to Last Visit**
Placebo	No.	13	12	12
	Mean (SD)	16.4 (29.4)	5.4 (9.6)	-12.2 (30.4)
	Median	1.4*	1.4*	0.0
	Range	1.4*/100.7	1.4*/31.0	-99.3/13.7
GL701 100mg/day	No.	14	13	13
	Mean (SD)	5.5 (10.9)	52.2 (76.2)	49.4§ (76.7)
	Median	1.4*	27.2	20.4
	Range	1.4*/41.5	1.4*/256.1	0.0/254.7
GL701 200 mg/day	No.	4	4	4
	Mean (SD)	25.6 (48.3)	154.9 (154.3)	129.3§§ (163.8)
	Median	1.4*	97.1	48.1
	Range	1.4*/98.0	48.9/376.4	46.0/375.0

[1] Baseline refers to the last pre-dose measurement.

[2] Last Visit refers to the last post-baseline measurement in the core study.

§P=0.0061, GL701 100mg vs. placebo, change from baseline to last visit, one way ANOVA

§§P=0.005, GL701 200mg vs. placebo, change from baseline to last visit, one-way ANOVA

Minimum measurable quantity.

Source: Tables 11.3.6.1 and 11.3.6.2, and 11.3.7 (Volume III)

TABLE 12

FSH/LH (mIU/ML) in Post-menopausal SLE Patients (Study GL94-01)							
Treatment Group		Baseline[1]		Last Visit[2]		Change from Baseline to Last Visit	
		FSH	LH	FSH	LH	FSH	LH
Placebo	No.	16	16	14	14	14	14
	Mean	91.6	38.9	101.9	36.6	15.2	3.7
	(SD)	(50.3)	(30.9)	(53.9)	(32.5)	(16.8)	(10.8)
	Median	98.5	27.5	93.0	23.5	8.5	1.0
	Range	11.0/185.0	6.0/107.0	19.0/213.0	9.0/133.0	-11.0/46.0	-16.0/26.0
GL701 100 mg/day	No.	17	17	15	15	15	15
	Mean	119.5	47.5	84.5	30.4	-23.1†	-4.5
	(SD)	(91.0)	(63.5)	(49.2)	(20.3)	(28.7)	(15.3)
	Median	95.0	30.0	89.0	33.0	-16.0	-3.0
	Range	21.0/395.0	5.0/279.0	10.0/171.0	2.0/81.0	-90.0/13.0	-50.0/15.0
GL701 200 mg/day	No.	7	7	7	7	7	7
	Mean	64.0	28.7	42.7	16.1	-21.3§	-12.6§§
	(SD)	(28.8)	(18.9)	(36.2)	(10.3)	(30.3)	(17.5)
	Median	63.0	34.0	23.0	15.0	-9.0	-6.0
	Range	13.0/112.0	3.0/54.0	2.0/103.0	2.0/30.0	-69.0/10.0	-44.0/5.0

[1]Baseline refers to the last pre-dose measurement.

[2]Last Visit refers to the last post-baseline measurement in the core study.

† P=0.0002, GL701 100 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

§ P=0.0035, GL701 200 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

§§ P=0.0183, GL701 200 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

Source: Tables 11.3.5.2-5a/b and 11.3.5.2-6a/b (Volume III)

TABLE 13

Testosterone (ng/dl) in Pre-menopausal SLE Patients (Study GL94-01)				
Treatment Group		Baseline[1]	Last Visit[2]	Change from Baseline to Last Visit
Placebo	No.	37	35	35
	Mean (SD)	20.8 (17.5)	19.3 (14.4)	-1.9 (15.3)
	Median	17.0	16.0	-2.0
	Range	4.0/95.0	4.0/64.0	-31.0/29.0
GL701 100mg/day	No.	37	36	36
	Mean (SD)	20.3 (15.6)	32.0 (19.0)	11.5 (18.4)
	Median	17.0	34.0	12.0
	Range	4.0/68.0	4.0/75.0	-26.0/54.0
GL701 200 mg/day	No.	47	43	42
	Mean (SD)	19.0 (13.3)	74.7 (58.2)	56.1 (60.8)
	Median	17.0	67.0	47.5
	Range	4.0/70.0	4.0/253.0	-30.0/220.0

[1] Baseline refers to the last pre-dose measurement.

[2] Last Visit refers to the last post-baseline measurement in the core study.

Source: Tables 9.4.2.1-1 (Table 12) and 9.4.2.1-2 (Table 13)

Testosterone (ng/dl) in Post-menopausal SLE Patients (Study GL94-01)				
Treatment Group		Baseline[1]	Last Visit[2]	Change from Baseline to Last Visit
Placebo	No.	16	14	14
	Mean (SD)	8.1 (6.2)	11.8 (17.4)	3.1 (11.8)
	Median	6.5	4.0	0.0
	Range	4.0/29.0	4.0/68.0	-7.0/39.0
GL701 100mg/day	No.	17	15	15
	Mean (SD)	12.1 (10.5)	39.0 (19.0)	27.7 (20.2)
	Median	8.0	34.0	27.0
	Range	4.0/40.0	14.0/80.0	-9.0/65.0
GL701 200 mg/day	No.	7	7	7
	Mean (SD)	14.7 (12.4)	105.0 (70.9)	90.3 (70.1)
	Median	10.0	106.0	73.0
	Range	4.0/33.0	10.0/208.0	3.0/202.0

[1] Baseline refers to the last pre-dose measurement.

[2] Last Visit refers to the last post-baseline measurement in the core study.

Source: Tables 9.4.2.1-1 (Table 12) and 9.4.2.1-2 (Table 13)

TABLE 14

Total Cholesterol (mg/dl) in SLE Patients (Study GL94-01)				
Treatment Group		**Baseline[1]**	**Last Visit[2]**	**Change from Baseline to Last Visit**
Placebo	No.	63	61	61
	Mean (SD)	210.9 (47.3)	192.4 (51.6)	-19.6 (42.6)
	Median	207.0	188.0	-19.0
	Range	139.0/337.0	94.0/397.0	-181.0/191.0
GL701 100mg/day	No.	63	61	61
	Mean (SD)	216.5 (45.4)	201.3 (41.9)	-13.3 (39.7)
	Median	212.0	201.0	-18.0
	Range	136.0/362.0	125.0/288.0	-112.0/138.0
GL701 200 mg/day	No.	63	58	57
	Mean (SD)	207.8 (45.6)	188.4 (67.1)	-20.5 (54.7)
	Median	201.0	171.0	-26.0
	Range	109.0/327.0	101.0/484.0	-111.0/219.0

LDL Cholesterol (mg/dl) in SLE Patients (Study GL94-01)				
Treatment Group		**Baseline[1]**	**Last Visit[2]**	**Change from Baseline to Last Visit**
Placebo	No.	63	60	60
	Mean (SD)	131.9 (33.2)	121.1 (38.4)	-11.4 (28.3)
	Median	131.0	120.0	-15.5
	Range	71.0/209.0	60.0/281.0	-50.0/152.0
GL701 100mg/day	No.	63	61	61
	Mean (SD)	138.8 (38.6)	135.1 (35.9)	-1.8 (31.2)
	Median	135.0	131.0	-9.0
	Range	63.0/268.0	63.0/235.0	-79.0/109.0
GL701 200 mg/day	No.	63	56	55
	Mean (SD)	130.0 (36.7)	123.8 (54.7)	-8.3 (41.0)
	Median	131.0	108.0	-12.0
	Range	58.0/232.0	50.0/417.0	-84.0/185.0

HDL Cholesterol (mg/dl) in SLE Patients (Study GL94-01)				
Treatment Group		**Baseline[1]**	**Last Visit[2]**	**Change from Baseline to Last Visit**
Placebo	No.	63	60	60
	Mean (SD)	54.5 (20.2)	49.0 (17.9)	-6.0 (11.8)
	Median	49.0	44.0	-4.5
	Range	30.0/129.0	21.0/119.0	-54.0/25.0
GL701 100 mg/day	No.	63	61	61
	Mean (SD)	51.9 (16.5)	43.9 (16.1)	-8.2 (14.8)
	Median	48.0	39.0	-9.0
	Range	28.0/96.0	21.0/92.0	-65.0/41.0
GL701 200 mg/day	No.	63	57	56
	Mean (SD)	53.8 (17.7)	40.0 (13.9)	-13.5§ (11.8)
	Median	50.0	36.0	-12.5
	Range	22.0/99.0	16.0/75.0	-34.0/18.0

[1]Baseline refers to the last pre-dose measurement.

[2]Last Visit refers to the last post-baseline measurement in the core study.

§ P=0.002, GL701 200 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

Tot-C/HDL-C Ratio in SLE Patients (Study GL94-01)				
Treatment Group		Baseline[1]	Last Visit[2]	Change from Baseline to Last Visit
Placebo	No.	63	60	60
	Mean (SD)	4.2 (1.2)	4.2 (1.2)	0.1 (0.7)
	Median	4.0	4.2	0.1
	Range	2.3/7.2	2.4/7.7	-1.3/2.3
GL701 100mg/day	No.	63	61	61
	Mean (SD)	4.5 (1.5)	5.1 (2.0)	0.7† (1.5)
	Median	4.4	4.7	0.5
	Range	2.1/9.3	2.0/11.6	-2.1/6.9
GL701 200 mg/day	No.	63	57	56
	Mean (SD)	4.2 (1.5)	5.3 (3.2)	1.1§ (2.6)
	Median	4.0	4.4	0.5
	Range	1.9/9 1	2.5/19.4	-2.1/12.2

[1] Baseline refers to the last pre-dose measurement.

[2] Last Visit refers to the last post-baseline measurement in the core study.

† P=0.003, GL701 100 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

§ P= 0.095, GL701 200 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

HDL-C (mg/dl) in Pre-menopausal SLE Patients (Study GL94-01)				
Treatment Group		Baseline[1]	Last Visit[2]	Change from Baseline to Last Visit
Placebo	No.	37	35	35
	Mean (SD)	49.3 (15.7)	45.9 (15.3)	-4.1 (8.0)
	Median	47.0	42.0	-4.0
	Range	30.0/114.0	21.0/105.0	-22.0/25.0
GL701 100mg/day	No.	37	36	36
	Mean (SD)	49.6 (14.1)	44.8 (16.8)	-4.9 (12.1)
	Median	48.0	39.5	-8.0
	Range	28.0/84.0	21.0/92.0	-26.0/41.0
GL701 200 mg/day	No.	47	42	41
	Mean (SD)	53.0 (16.0)	38.2 (11.6)	-13.7§ (11.21)
	Median	48.0	35.5	-13.0
	Range	30.0/99.0	17.0/75.0	-34.0/12.0

[1] Baseline refers to the last pre-dose measurement.

[2] Last Visit refers to the last post-baseline measurement in the core study.

§ P = 0.001, GL701 200 mg vs. Placebo for change from baseline at last visit, one-way ANOVA.

Source: Tables 9.4.2.1-1 (Table 12) and 9.4.2.1-2 (Table 13)

HDL-C (mg/dl) in Postmenopausal SLE Patients (Study GL94-01)				
Treatment Group		Baseline[1]	Last Visit[2]	Change from Baseline to Last Visit
Placebo	No.	16	15	15
	Mean (SD)	62.9 (26.7)	54.6 (23.1)	-8.8 (15.0)
	Median	56.5	48.0	-9.0
	Range	39.0/129.0	30.0/119.0	-54.0/12.0
GL701 100mg/day	No.	17	16	16
	Mean (SD)	53.0 (16.4)	38.6 (12.1)	-15.3 (19.5)
	Median	53.0	36.5	-12.5
	Range	33.0/93.0	23.0/70.0	-65.0/16.0
GL701 200 mg/day	No.	7	7	7
	Mean (SD)	49.4 (26.0)	39.4 (20.8)	-10.0 (17.4)
	Median	41.0	26.0	-7.0
	Range	22.0/92.0	16.0/63.0	-33.0/18.0

[1] Baseline refers to the last pre-dose measurement.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Serum Glucose (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	55	53	50	49	63
	Mean	14.1	12.4	10.8	18.6	11.5	11.7	5.8	6.4
	SD	27.70	27.17	27.60	45.96	28.51	31.84	23.02	21.27
	Min	-24.0	-26.0	-45.0	-31.0	-46.0	-32.0	-29.0	-29.0
	Median	10.5	5.5	9.0	7.0	6.0	8.0	1.0	3.0
	Max	125.0	101.0	115.0	239.0	123.0	122.0	104.0	104.0
GL701 100mg									
	Number	61	61	60	56	51	52	47	63
	Mean	10.9	8.9	7.9	8.7	8.1	8.8	3.7	7.1
	SD	18.95	18.30	17.97	16.69	18.61	20.32	22.92	24.03
	Min	-25.0	-31.0	-33.0	-24.0	-22.0	-39.0	-37.0	-37.0
	Median	8.0	8.0	6.0	7.5	6.0	6.0	0.0	2.0
	Max	93.0	68.0	65.0	81.0	81.0	89.0	129.0	129.0
GL701 200mg									
	Number	63	62	57	56	53	51	43	63
	Mean	14.0	8.6	3.6	2.4	1.8	-0.5	-5.7	-3.4
	SD	41.77	37.45	33.62	29.42	32.27	35.14	29.33	24.35
	Min	-102.0	-61.0	-141.0	-109.0	-154.0	-165.0	-122.0	-122.0
	Median	5.0	4.0	3.0	3.0	1.0	0.0	-2.0	-2.0
	Max	257.0	248.0	155.0	63.0	78.0	145.0	60.0	43.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

TABLE 15

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Serum Uric Acid (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	54	50	49	63
	Mean	-0.1	-0.2	-0.1	-0.2	0.0	-0.1	0.1	-0.0
	SD	0.95	1.06	1.04	0.95	1.10	0.99	0.89	0.92
	Min	-4.8	-5.4	-5.0	-4.3	-2.8	-2.6	-2.1	-2.8
	Median	0.0	-0.2	-0.1	0.0	0.1	-0.1	0.0	0.0
	Max	1.6	1.6	2.0	1.7	2.4	3.0	2.8	2.8
GL701 100mg									
	Number	63	62	60	56	53	52	47	63
	Mean	0.1	0.2	0.4	0.3	0.3	0.4	0.4	0.3
	SD	0.98	1.15	0.88	0.87	1.07	0.93	1.04	1.32
	Min	-4.0	-5.0	-1.5	-1.3	-1.4	-1.1	-1.6	-5.0
	Median	0.2	0.3	0.5	0.2	0.1	0.3	0.2	0.2
	Max	2.4	3.8	3.7	3.6	3.4	2.8	3.2	3.7
GL701 200mg									
	Number	63	62	59	57	55	51	43	63
	Mean	-0.2	-0.1	-0.0	0.0	0.0	0.1	-0.0	0.0
	SD	1.23	1.44	1.15	1.27	1.40	1.68	1.27	1.41
	Min	-4.6	-4.9	-4.6	-5.0	-5.4	-5.2	-4.7	-4.7
	Median	-0.2	0.0	0.0	0.2	0.2	0.0	0.3	0.1
	Max	6.4	6.2	5.2	5.7	5.3	6.1	2.8	6.1

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Serum Creatinine-QT (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	54	50	49	63
	Mean	0.0	0.0	0.0	-0.0	-0.0	-0.0	-0.0	-0.0
	SD	0.11	0.13	0.12	0.13	0.11	0.13	0.12	0.14
	Min	-0.3	-0.3	-0.2	-0.3	-0.2	-0.3	-0.3	-0.3
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	0.3	0.4	0.5	0.5	0.3	0.3	0.2	0.5
GL701 100mg									
	Number	63	62	60	56	53	52	47	63
	Mean	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1
	SD	0.18	0.30	0.27	0.16	0.14	0.18	0.25	0.33
	Min	-0.5	-0.3	-0.3	-0.2	-0.2	-0.2	-0.2	-0.3
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	0.9	1.9	1.9	0.6	0.5	0.9	1.4	1.9
GL701 200mg									
	Number	63	62	59	57	55	51	43	63
	Mean	-0.2	-0.2	-0.2	-0.1	-0.2	-0.2	-0.2	-0.1
	SD	1.64	1.70	1.62	1.62	1.77	1.81	1.81	1.49
	Min	-12.9	-13.3	-12.4	-12.1	-13.0	-12.8	-11.7	-11.7
	Median	0.0	0.0	0.0	0.1	0.1	0.0	0.1	0.1
	Max	0.3	0.4	0.4	0.5	1.1	0.9	0.6	0.6

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

nml < 2'

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Creatine Kinase (U/L)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	53	50	49	63
	Mean	5.6	7.3	9.8	17.0	10.6	9.9	12.0	16.9
	SD	18.96	22.25	25.50	60.12	30.70	32.83	26.37	53.90
	Min	-49.0	-49.0	-62.0	-55.0	-78.0	-77.0	-68.0	-68.0
	Median	4.0	3.0	7.0	5.5	6.0	6.0	10.0	8.0
	Max	70.0	132.0	88.0	394.0	149.0	135.0	80.0	394.0
GL701 100mg									
	Number	63	62	60	56	52	52	47	63
	Mean	6.5	15.3	8.5	27.0	19.2	35.4	23.7	17.8
	SD	30.44	57.21	33.55	97.68	41.44	123.50	40.69	37.30
	Min	-163.0	-155.0	-132.0	-105.0	-78.0	-133.0	-123.0	-123.0
	Median	5.0	6.5	4.5	10.0	13.5	13.0	18.0	13.0
	Max	128.0	286.0	115.0	700.0	256.0	870.0	152.0	152.0
GL701 200mg									
	Number	63	62	59	56	54	51	43	63
	Mean	2.0	7.7	8.3	7.9	10.8	8.3	15.9	16.4
	SD	37.42	49.76	47.97	49.11	50.47	49.06	83.08	70.37
	Min	-242.0	-273.0	-272.0	-256.0	-241.0	-248.0	-257.0	-257.0
	Median	4.0	9.0	9.0	10.0	9.0	13.0	16.0	14.0
	Max	69.0	194.0	170.0	170.0	159.0	138.0	430.0	430.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

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Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Urea Nitrogen (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	54	50	49	63
	Mean	-0.3	-0.5	-0.7	-0.7	-0.2	-0.3	-0.6	-0.9
	SD	3.70	4.85	4.60	4.73	4.59	3.79	5.14	5.04
	Min	-12.0	-17.0	-18.0	-15.0	-14.0	-15.0	-16.0	-16.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	7.0	10.0	8.0	6.0	12.0	6.0	11.0	11.0
GL701 100mg									
	Number	63	62	60	56	53	52	47	63
	Mean	-1.3	-1.1	-0.2	-0.6	-0.4	-0.3	1.3	0.8
	SD	6.49	9.58	8.65	6.96	5.97	5.65	8.65	11.05
	Min	-25.0	-37.0	-26.0	-38.0	-23.0	-19.0	-14.0	-37.0
	Median	-1.0	-1.0	-0.5	0.0	0.0	-0.5	0.0	-1.0
	Max	23.0	43.0	43.0	16.0	16.0	15.0	40.0	43.0
GL701 200mg									
	Number	63	62	59	57	55	51	43	63
	Mean	-1.4	-1.8	-1.9	-1.2	-1.6	-0.9	-1.6	-0.9
	SD	7.32	9.30	9.82	10.13	9.48	11.78	10.14	9.58
	Min	-47.0	-64.0	-66.0	-54.0	-56.0	-53.0	-54.0	-54.0
	Median	-1.0	-1.0	-1.0	0.0	-2.0	-1.0	-2.0	-1.0
	Max	20.0	18.0	20.0	25.0	20.0	44.0	21.0	26.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Calcium (EDTA) (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	54	50	49	63
	Mean	0.0	0.1	-0.0	-0.0	-0.1	-0.1	-0.1	-0.1
	SD	0.44	0.51	0.48	0.47	0.48	0.54	0.50	0.45
	Min	-1.3	-1.1	-1.2	-1.4	-1.4	-1.6	-1.8	-1.8
	Median	0.0	0.0	-0.1	0.0	-0.1	-0.2	-0.1	-0.1
	Max	1.4	1.4	1.1	1.3	1.2	1.2	0.8	0.8
GL701 100mg									
	Number	63	62	60	56	53	52	47	63
	Mean	0.1	0.0	0.1	0.0	0.0	0.0	-0.0	-0.0
	SD	0.46	0.37	0.43	0.51	0.69	0.45	0.62	0.61
	Min	-0.9	-0.6	-0.9	-1.3	-3.4	-1.1	-1.0	-1.0
	Median	0.1	0.0	0.1	0.0	0.0	0.0	-0.1	-0.1
	Max	1.5	1.2	0.9	1.3	1.6	1.2	3.4	3.4
GL701 200mg									
	Number	63	62	59	57	55	51	43	63
	Mean	-0.0	-0.1	0.0	-0.0	-0.0	-0.1	-0.2	-0.1
	SD	0.50	0.48	0.45	0.48	0.46	0.44	0.48	0.51
	Min	-1.5	-1.2	-1.0	-1.1	-0.9	-1.3	-1.1	-1.1
	Median	-0.1	-0.0	0.1	0.0	0.0	0.0	-0.2	-0.2
	Max	1.1	1.0	1.0	1.1	1.1	0.9	0.9	1.1

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Phosphorus (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	53	49	49	63
	Mean	-0.0	-0.0	-0.1	-0.1	-0.1	0.0	0.0	0.0
	SD	0.69	0.66	0.68	0.63	0.71	0.73	0.67	0.66
	Min	-1.7	-1.6	-1.6	-1.6	-1.8	-1.5	-1.3	-1.3
	Median	-0.1	0.0	-0.1	-0.1	0.0	-0.1	0.0	0.0
	Max	1.9	1.7	1.2	1.3	1.4	2.0	1.5	1.5
GL701 100mg									
	Number	61	62	60	56	51	52	47	63
	Mean	-0.3	-0.1	-0.1	-0.2	-0.2	-0.2	-0.0	0.0
	SD	0.76	0.78	0.79	0.69	0.77	0.61	0.70	0.82
	Min	-2.4	-1.5	-2.4	-1.7	-2.4	-1.5	-1.7	-1.7
	Median	-0.4	-0.0	0.0	-0.3	-0.4	-0.3	-0.1	-0.2
	Max	1.3	2.0	2.0	1.4	1.6	1.0	1.6	2.0
GL701 200mg									
	Number	62	62	59	57	53	51	43	63
	Mean	-0.2	-0.4	-0.3	-0.3	-0.2	-0.1	-0.2	-0.1
	SD	0.79	0.66	0.65	0.61	0.69	0.65	0.73	0.72
	Min	-1.8	-2.5	-1.6	-1.4	-1.8	-1.7	-1.7	-1.7
	Median	-0.1	-0.4	-0.3	-0.2	-0.1	-0.1	-0.1	-0.1
	Max	2.0	1.0	1.1	1.4	1.1	1.2	1.6	1.6

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Total Protein (g/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo	Number	62	62	59	56	54	50	49	63
	Mean	0.1	0.0	-0.0	0.0	-0.0	-0.1	-0.1	-0.0
	SD	0.64	0.56	0.56	0.63	0.45	0.63	0.51	0.50
	Min	-1.0	-0.8	-1.1	-1.1	-1.3	-2.0	-1.6	-1.6
	Median	0.0	0.0	-0.1	0.0	0.0	0.0	0.0	0.0
	Max	3.6	3.1	2.9	3.0	0.9	1.6	1.1	1.1
GL701 100mg	Number	63	62	60	56	53	52	47	63
	Mean	-0.1	-0.1	-0.0	-0.0	-0.0	-0.1	-0.1	-0.1
	SD	0.54	0.55	0.53	0.53	0.60	0.55	0.55	0.58
	Min	-1.9	-2.2	-2.0	-1.8	-2.2	-2.1	-1.6	-1.7
	Median	0.1	0.0	-0.0	0.0	0.0	-0.1	-0.1	-0.1
	Max	1.1	1.3	0.9	1.2	1.4	0.8	1.0	1.3
GL701 200mg	Number	63	62	59	57	55	51	43	63
	Mean	-0.0	0.0	-0.0	-0.0	-0.0	-0.2	-0.1	-0.1
	SD	0.60	0.57	0.61	0.62	0.67	0.67	0.89	0.77
	Min	-2.6	-2.6	-2.4	-2.8	-3.0	-3.4	-3.5	-3.5
	Median	0.0	-0.1	0.1	0.0	0.0	-0.2	-0.1	-0.1
	Max	1.9	1.2	1.5	1.6	1.6	1.4	2.0	2.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Albumin (g/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	53	50	49	63
	Mean	0.0	-0.0	-0.0	-0.1	-0.1	-0.1	-0.1	-0.1
	SD	0.34	0.31	0.30	0.34	0.38	0.44	0.38	0.37
	Min	-0.8	-0.8	-0.7	-0.8	-1.0	-1.5	-1.6	-1.6
	Median	0.0	0.0	-0.1	0.0	-0.1	-0.1	-0.1	-0.1
	Max	1.4	1.2	1.0	0.9	0.9	0.7	0.5	0.9
GL701 100mg									
	Number	63	62	60	56	52	52	47	63
	Mean	-0.0	0.0	0.0	-0.0	-0.0	-0.1	-0.0	-0.1
	SD	0.29	0.36	0.30	0.30	0.30	0.31	0.33	0.36
	Min	-1.0	-0.9	-0.8	-0.8	-1.1	-1.0	-0.7	-0.9
	Median	0.0	0.0	0.0	0.0	0.0	-0.1	0.0	-0.1
	Max	0.6	0.9	0.8	0.7	0.6	0.5	0.8	0.8
GL701 200mg									
	Number	63	62	59	56	54	51	43	63
	Mean	-0.0	0.0	-0.0	-0.0	-0.0	-0.1	-0.1	-0.1
	SD	0.32	0.32	0.37	0.36	0.36	0.37	0.48	0.45
	Min	-1.0	-1.0	-0.9	-1.1	-1.3	-1.7	-1.8	-1.8
	Median	0.0	0.0	0.0	0.0	0.0	-0.1	0.0	0.0
	Max	1.0	0.7	1.1	0.7	0.7	0.6	0.9	0.9

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Total Bilirubin (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	53	50	49	63
	Mean	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0
	SD	0.14	0.17	0.18	0.21	0.17	0.27	0.14	0.13
	Min	-0.8	-1.0	-1.0	-1.3	-0.8	-1.6	-0.3	-0.3
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	0.2	0.3	0.3	0.3	0.5	0.4	0.3	0.3
GL701 100mg									
	Number	63	62	60	56	52	52	47	63
	Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	SD	0.13	0.16	0.13	0.13	0.12	0.13	0.15	0.16
	Min	-0.3	-0.4	-0.3	-0.2	-0.2	-0.3	-0.2	-0.2
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	0.4	0.4	0.3	0.3	0.4	0.3	0.4	0.6
GL701 200mg									
	Number	63	62	59	56	54	51	43	63
	Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	SD	0.21	0.15	0.14	0.16	0.14	0.16	0.13	0.15
	Min	-0.6	-0.6	-0.6	-0.5	-0.6	-0.5	-0.2	-0.5
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	0.9	0.6	0.3	0.7	0.3	0.5	0.4	0.4

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: Alkaline Phosphatase (U/L)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	54	49	49	63
	Mean	-0.0	-0.2	-0.3	0.2	1.0	-0.0	4.4	2.6
	SD	14.52	12.60	16.20	16.69	18.02	19.80	15.70	18.61
	Min	-44.0	-45.0	-71.0	-82.0	-78.0	-87.0	-43.0	-87.0
	Median	1.0	1.0	0.0	1.0	0.5	2.0	5.0	4.0
	Max	71.0	40.0	31.0	39.0	48.0	51.0	45.0	45.0
GL701 100mg									
	Number	63	62	60	56	53	52	47	63
	Mean	-1.5	-1.9	-1.8	1.5	2.8	1.2	3.5	1.1
	SD	12.70	12.39	14.02	10.18	11.78	11.33	15.39	18.24
	Min	-66.0	-50.0	-68.0	-19.0	-21.0	-24.0	-34.0	-68.0
	Median	0.0	0.0	1.0	2.0	3.0	1.0	2.0	2.0
	Max	25.0	20.0	31.0	24.0	36.0	31.0	51.0	51.0
GL701 200mg									
	Number	62	62	59	57	55	51	43	63
	Mean	-1.6	-0.4	3.3	4.5	3.2	3.1	6.2	5.9
	SD	10.20	10.79	16.48	20.03	15.33	14.36	17.89	18.96
	Min	-31.0	-24.0	-32.0	-31.0	-26.0	-38.0	-25.0	-25.0
	Median	0.0	0.0	1.0	2.0	3.0	3.0	3.0	3.0
	Max	22.0	26.0	67.0	90.0	43.0	44.0	63.0	77.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: ALT (SGPT) (U/L)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	54	50	49	63
	Mean	-0.4	-2.5	-4.0	-3.8	-2.5	-1.6	-1.8	-1.4
	SD	13.33	10.33	11.62	8.65	11.10	11.03	13.89	13.29
	Min	-29.0	-46.0	-48.0	-36.0	-35.0	-33.0	-37.0	-37.0
	Median	-1.0	-2.0	-2.0	-2.5	-2.0	-2.0	-2.0	-1.0
	Max	72.0	35.0	28.0	19.0	53.0	38.0	65.0	65.0
GL701 100mg									
	Number	63	62	60	56	53	52	47	63
	Mean	-1.5	0.8	-1.7	-1.0	-0.2	-1.3	0.9	2.5
	SD	7.55	14.36	6.27	10.40	14.35	8.84	14.96	16.48
	Min	-33.0	-34.0	-25.0	-33.0	-24.0	-34.0	-34.0	-34.0
	Median	-1.0	-1.5	-1.0	-1.0	-2.0	-1.0	0.0	0.0
	Max	20.0	70.0	16.0	44.0	87.0	16.0	57.0	64.0
GL701 200mg									
	Number	63	62	59	56	55	51	43	63
	Mean	3.3	1.7	-0.6	0.2	-0.7	1.8	-3.8	-1.7
	SD	39.11	25.57	10.19	13.05	13.50	24.56	11.36	14.18
	Min	-19.0	-27.0	-25.0	-25.0	-32.0	-32.0	-43.0	-43.0
	Median	-1.0	-1.0	-1.0	-0.5	-2.0	-1.0	-3.0	-1.0
	Max	302.0	187.0	34.0	61.0	53.0	121.0	26.0	61.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

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Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CHEMISTRY: AST (SGOT) (U/L)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	62	62	59	56	54	50	49	63
	Mean	-0.1	-0.6	-1.5	-1.3	1.1	0.9	1.4	1.6
	SD	9.38	9.40	9.68	7.03	11.23	9.77	9.95	10.04
	Min	-33.0	-46.0	-49.0	-33.0	-28.0	-30.0	-32.0	-32.0
	Median	1.0	0.5	0.0	-1.0	-0.5	0.0	1.0	1.0
	Max	38.0	19.0	17.0	12.0	54.0	35.0	48.0	48.0
GL701 100mg									
	Number	63	62	60	56	53	52	47	63
	Mean	-0.9	0.3	-1.3	0.3	0.6	0.1	1.1	1.7
	SD	3.78	9.03	5.63	10.38	9.22	6.65	9.04	11.24
	Min	-14.0	-14.0	-17.0	-22.0	-23.0	-22.0	-23.0	-17.0
	Median	-1.0	-1.0	-1.0	0.5	0.0	0.0	1.0	1.0
	Max	8.0	55.0	16.0	61.0	49.0	18.0	32.0	61.0
GL701 200mg									
	Number	63	62	59	56	55	51	43	63
	Mean	3.6	1.1	-0.5	2.7	1.6	2.9	-0.4	2.4
	SD	33.95	21.13	9.99	21.66	11.82	22.51	8.54	19.46
	Min	-11.0	-19.0	-16.0	-17.0	-18.0	-18.0	-21.0	-21.0
	Median	-1.0	-1.0	-1.0	-1.0	1.0	0.0	1.0	1.0
	Max	265.0	158.0	60.0	139.0	60.0	116.0	33.0	139.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

HEMATOLOGY: RBC (x1000000/uL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	59	60	57	53	51	48	47	61
	Mean	-0.0	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1
	SD	0.24	0.26	0.27	0.29	0.35	0.36	0.38	0.35
	Min	-0.8	-0.9	-0.9	-0.7	-1.0	-0.9	-0.8	-0.8
	Median	0.0	0.0	-0.1	-0.1	-0.1	0.0	-0.1	0.0
	Max	0.4	0.4	0.5	0.5	0.5	0.5	0.8	0.8
GL701 100mg									
	Number	62	62	60	56	51	52	45	63
	Mean	0.1	0.0	0.1	0.0	0.0	-0.0	-0.0	-0.0
	SD	0.25	0.28	0.28	0.28	0.35	0.29	0.36	0.35
	Min	-0.6	-0.7	-0.9	-0.8	-1.2	-1.2	-1.1	-1.2
	Median	0.1	0.0	0.0	0.1	0.1	0.0	0.0	0.0
	Max	0.7	0.8	0.7	0.6	0.9	0.7	0.7	0.7
GL701 200mg									
	Number	62	63	59	57	53	52	44	64
	Mean	0.0	0.1	0.1	0.1	0.1	-0.0	0.0	0.0
	SD	0.31	0.26	0.36	0.39	0.34	0.31	0.38	0.34
	Min	-0.6	-0.5	-0.5	-0.8	-0.6	-0.6	-0.6	-0.6
	Median	0.0	0.0	0.0	0.0	0.0	-0.1	0.0	0.0
	Max	0.8	0.8	1.2	1.2	1.2	1.1	1.0	1.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

HEMATOLOGY: WBC (x1000/uL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo	Number	59	60	57	53	51	48	47	61
	Mean	0.9	0.7	0.3	0.2	-0.3	-0.2	-0.7	-0.4
	SD	2.06	2.51	1.75	2.21	2.23	2.53	1.98	2.26
	Min	-4.3	-4.9	-2.9	-5.3	-5.3	-5.7	-5.6	-5.6
	Median	0.9	0.4	0.2	-0.1	-0.5	-0.3	-0.7	-0.7
	Max	6.9	9.2	5.0	5.3	8.6	7.8	3.8	8.6
GL701 100mg	Number	62	62	60	56	51	52	45	63
	Mean	0.3	0.4	0.4	0.1	-0.1	-0.4	-0.6	-0.3
	SD	1.90	1.95	2.13	1.88	2.28	2.30	2.00	2.34
	Min	-4.0	-4.4	-3.2	-4.6	-9.2	-5.7	-7.0	-7.0
	Median	0.0	0.2	0.2	-0.1	0.1	-0.4	-0.2	-0.1
	Max	5.7	5.9	7.3	4.5	4.8	7.4	3.2	7.4
GL701 200mg	Number	62	63	59	57	53	52	44	64
	Mean	0.6	-0.0	0.0	-0.2	-0.3	-0.5	-1.0	-0.9
	SD	2.53	2.32	2.79	2.30	2.11	2.34	2.22	2.53
	Min	-6.1	-5.9	-5.1	-7.0	-4.9	-5.4	-6.0	-7.0
	Median	0.4	0.2	-0.1	0.0	0.0	-0.2	-0.8	-0.6
	Max	10.9	6.6	8.6	5.0	3.7	6.3	2.5	6.3

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

HEMATOLOGY: Platelets (x1000/uL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	58	59	56	53	50	47	46	61
	Mean	3.9	5.2	10.5	1.1	-1.6	2.5	4.3	6.2
	SD	36.23	50.45	51.89	49.25	47.46	64.23	56.69	59.79
	Min	-96.0	-110.0	-83.0	-118.0	-119.0	-132.0	-134.0	-134.0
	Median	5.0	-6.0	7.5	-6.0	-4.0	-9.0	0.0	4.0
	Max	83.0	183.0	182.0	134.0	116.0	183.0	175.0	175.0
GL701 100mg									
	Number	62	61	60	56	51	52	45	63
	Mean	18.1	6.1	15.1	5.3	9.5	-1.2	6.5	10.2
	SD	41.13	39.44	44.82	40.67	39.40	35.83	42.81	46.92
	Min	-76.0	-122.0	-100.0	-85.0	-55.0	-97.0	-75.0	-100.0
	Median	12.0	5.0	18.0	-6.0	7.0	2.5	2.0	5.0
	Max	183.0	102.0	143.0	122.0	106.0	96.0	111.0	124.0
GL701 200mg									
	Number	61	63	59	57	53	52	43	64
	Mean	17.3	-1.6	7.1	-1.4	-6.2	-11.8	-10.7	-12.0
	SD	45.03	45.69	43.90	44.25	52.01	51.18	50.52	55.85
	Min	-88.0	-158.0	-107.0	-116.0	-158.0	-163.0	-127.0	-158.0
	Median	19.0	-4.0	7.0	-6.0	-7.0	-6.0	-7.0	-7.5
	Max	110.0	96.0	105.0	109.0	110.0	112.0	83.0	102.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

HEMATOLOGY: Monocytes (%)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	56	60	57	52	51	47	47	61
	Mean	-0.3	-0.7	-1.2	-1.1	-1.7	-2.4	-1.9	-1.5
	SD	2.49	2.73	2.83	2.74	3.31	3.28	3.55	3.51
	Min	-6.0	-8.0	-8.0	-7.0	-10.0	-10.0	-9.0	-9.0
	Median	0.0	0.0	-1.0	-1.0	-1.0	-2.0	-2.0	-2.0
	Max	5.0	4.0	6.0	4.0	4.0	4.0	7.0	7.0
GL701 100mg									
	Number	61	62	60	55	51	52	45	63
	Mean	0.6	0.2	0.4	-0.2	-0.4	-0.4	-0.4	-0.4
	SD	2.45	2.47	2.53	2.86	3.27	2.82	3.39	3.28
	Min	-6.0	-6.0	-9.0	-8.0	-12.0	-12.0	-11.0	-12.0
	Median	1.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0
	Max	7.0	7.0	6.0	5.0	8.0	8.0	6.0	6.0
GL701 200mg									
	Number	59	63	59	57	53	52	44	64
	Mean	0.9	0.6	1.2	0.7	0.7	-0.2	0.6	0.3
	SD	3.07	2.99	3.76	4.00	3.34	3.39	3.88	3.62
	Min	-6.0	-6.0	-7.0	-8.0	-7.0	-7.0	-9.0	-9.0
	Median	1.0	0.0	0.0	1.0	0.0	-0.5	0.0	0.0
	Max	8.0	9.0	13.0	12.0	10.0	13.0	10.0	11.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

HEMATOLOGY: Eosinophils (%)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	59	60	57	53	51	48	47	61
	Mean	-5.6	-5.6	-4.2	-4.4	-0.9	-3.7	-1.2	-1.9
	SD	9.97	9.36	9.28	10.35	9.77	8.34	10.28	10.40
	Min	-27.7	-26.6	-25.5	-31.9	-20.0	-21.5	-19.9	-31.9
	Median	-6.9	-4.1	-3.9	-3.5	-0.1	-3.3	-2.9	-2.0
	Max	30.4	10.8	13.9	21.4	18.1	14.3	26.3	26.3
GL701 100mg									
	Number	62	62	60	56	51	52	45	63
	Mean	-3.9	-4.0	-2.9	-1.4	-3.4	-3.6	-0.6	-1.5
	SD	10.62	10.66	9.38	10.37	9.51	11.03	9.55	10.11
	Min	-29.2	-38.3	-31.4	-31.7	-29.7	-30.2	-32.0	-32.0
	Median	-1.7	-0.8	-2.1	-1.9	-3.7	-1.6	-0.7	-1.1
	Max	18.3	13.3	17.1	29.5	26.6	18.5	25.0	25.0
GL701 200mg									
	Number	62	63	59	57	53	52	44	64
	Mean	-3.8	-2.3	-2.2	-2.4	0.1	0.7	1.9	1.0
	SD	12.38	10.33	9.34	12.14	11.52	11.21	10.98	11.25
	Min	-38.9	-34.3	-35.7	-36.4	-29.7	-37.1	-29.4	-35.6
	Median	-1.5	-1.5	-0.3	-1.5	-0.2	1.2	1.5	0.1
	Max	22.2	25.6	13.1	30.9	24.9	26.2	26.9	26.9

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

HEMATOLOGY: Bands (%)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	59	60	57	53	51	48	47	61
	Mean	6.5	6.1	4.4	4.5	0.7	3.5	0.6	1.7
	SD	11.62	11.09	10.81	12.23	11.61	9.73	11.61	11.87
	Min	-31.8	-11.7	-14.0	-24.2	-22.4	-16.6	-29.9	-29.9
	Median	6.4	4.6	3.3	3.7	-0.2	3.3	-0.7	0.3
	Max	32.6	31.9	29.9	37.2	23.1	23.1	21.3	37.2
GL701 100mg									
	Number	62	62	60	56	51	52	45	63
	Mean	4.3	4.2	3.2	0.8	3.3	3.4	-0.1	1.1
	SD	12.70	12.53	10.89	12.46	11.26	12.89	10.91	11.87
	Min	-24.5	-18.9	-18.7	-37.3	-30.9	-17.1	-28.6	-28.6
	Median	2.8	0.6	2.8	2.1	4.8	1.7	0.5	1.1
	Max	33.4	45.0	34.8	35.8	31.3	36.5	38.2	38.2
GL701 200mg									
	Number	62	63	59	57	53	52	44	64
	Mean	4.5	2.2	1.9	1.7	-0.7	-1.7	-3.0	-1.7
	SD	14.61	12.38	11.10	14.28	14.21	13.16	13.14	13.21
	Min	-28.2	-36.5	-20.0	-35.4	-33.0	-27.8	-32.9	-32.9
	Median	2.1	0.3	0.5	0.1	-0.2	-2.4	-3.0	-1.4
	Max	43.9	39.3	38.9	38.3	34.6	42.4	34.0	38.3

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

HEMATOLOGY: Hemoglobin (g/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	59	60	57	53	51	48	47	61
	Mean	-0.1	-0.3	-0.5	-0.5	-0.6	-0.9	-0.8	-0.7
	SD	0.71	0.75	0.82	0.90	0.97	1.10	1.04	1.04
	Min	-1.8	-3.5	-3.4	-3.4	-3.0	-3.8	-3.2	-3.2
	Median	-0.1	-0.2	-0.4	-0.4	-0.5	-0.7	-0.5	-0.4
	Max	1.6	1.2	0.9	0.8	1.0	1.0	1.1	1.2
GL701 100mg									
	Number	62	62	60	56	51	52	45	63
	Mean	0.1	0.0	0.1	-0.1	-0.2	-0.3	-0.2	-0.3
	SD	0.72	0.77	0.84	0.81	1.03	0.84	1.10	1.06
	Min	-2.0	-1.8	-2.3	-2.5	-4.0	-3.5	-3.1	-4.0
	Median	0.0	0.1	0.0	-0.1	-0.2	-0.2	0.0	-0.2
	Max	2.3	1.9	2.4	1.6	2.1	1.6	2.4	2.4
GL701 200mg									
	Number	62	63	59	57	53	52	44	64
	Mean	0.1	0.2	0.4	0.3	0.2	-0.0	0.2	0.1
	SD	0.92	0.73	1.16	1.30	1.23	1.12	1.38	1.21
	Min	-1.4	-1.6	-1.4	-2.6	-2.6	-2.1	-2.8	-2.8
	Median	0.0	0.1	0.2	0.1	0.3	-0.2	-0.0	0.0
	Max	2.5	2.0	4.3	3.7	3.7	4.0	3.9	3.3

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

URINALYSIS: WBC/HPF

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	53	56	53	50	48	46	43	57
	Mean	0.9	-0.8	-0.8	1.7	1.4	2.9	1.0	1.1
	SD	8.37	3.98	5.48	9.16	6.37	13.71	9.10	10.54
	Min	-20.0	-22.0	-25.0	-12.0	-24.0	-24.0	-24.0	-25.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	43.0	7.0	6.0	46.0	25.0	73.0	39.0	46.0
GL701 100mg									
	Number	51	52	51	47	43	44	39	53
	Mean	1.7	2.9	0.7	0.1	2.4	0.2	0.5	1.6
	SD	11.73	12.59	5.73	3.67	11.73	4.69	4.41	10.58
	Min	-15.0	-15.0	-12.0	-15.0	-11.0	-12.0	-12.0	-12.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	71.0	72.0	25.0	10.0	68.0	16.0	13.0	72.0
GL701 200mg									
	Number	57	56	53	51	49	47	39	58
	Mean	-0.5	0.1	-0.7	3.7	3.7	0.4	5.4	0.7
	SD	5.70	7.77	6.45	17.22	17.13	8.14	20.54	10.70
	Min	-32.0	-31.0	-33.0	-31.0	-28.0	-32.0	-33.0	-33.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	12.0	25.0	16.0	75.0	75.0	26.0	75.0	57.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

URINALYSIS: RBC/HPF

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	52	53	51	49	46	45	42	54
	Mean	0.2	-1.0	-0.0	1.4	-1.0	-1.8	-0.3	-1.0
	SD	9.49	17.34	18.45	14.68	10.17	10.57	14.57	17.11
	Min	-57.0	-70.0	-73.0	-67.0	-62.0	-67.0	-62.0	-73.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	23.0	75.0	75.0	71.0	15.0	12.0	67.0	67.0
GL701 100mg									
	Number	50	51	50	47	42	43	38	53
	Mean	6.0	6.4	2.8	0.2	2.9	3.7	-1.4	0.3
	SD	18.89	21.33	13.31	16.87	13.62	13.09	5.56	15.98
	Min	-18.0	-18.0	-18.0	-74.0	-26.0	-14.0	-22.0	-74.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	75.0	75.0	65.0	75.0	65.0	65.0	6.0	75.0
GL701 200mg									
	Number	56	54	52	50	48	46	39	56
	Mean	3.0	4.6	-0.2	1.3	-0.5	4.8	5.5	3.8
	SD	19.18	23.06	11.23	20.82	18.23	23.50	26.84	22.05
	Min	-72.0	-75.0	-56.0	-69.0	-75.0	-75.0	-74.0	-74.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	75.0	75.0	46.0	75.0	75.0	75.0	75.0	75.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

24 HOUR URINE: Creatinine Clearance-QT (mL/min/1.73mE2)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	4	1	4	5	3	26	41
	Mean	18.5	17.8	-40.0	-10.0	-15.6	3.7	7.8	1.9
	SD	3.54	35.14	.	28.18	19.19	21.50	30.81	31.61
	Min	16.0	-18.0	-40.0	-45.0	-45.0	-20.0	-64.0	-64.0
	Median	18.5	12.0	-40.0	-9.5	-6.0	9.0	5.0	-1.0
	Max	21.0	65.0	-40.0	24.0	0.0	22.0	103.0	103.0
GL701 100mg									
	Number	5	6	4	3	6	6	18	37
	Mean	-8.4	-12.0	14.0	8.7	-18.0	6.8	1.0	3.9
	SD	23.64	20.26	10.42	16.50	32.48	9.24	31.34	48.73
	Min	-39.0	-35.0	4.0	-8.0	-68.0	-3.0	-44.0	-68.0
	Median	-9.0	-12.0	14.5	9.0	-13.0	4.5	-1.0	0.0
	Max	25.0	19.0	23.0	25.0	22.0	20.0	74.0	242.0
GL701 200mg									
	Number	7	7	4	3	5	5	24	37
	Mean	10.0	-6.4	13.8	-20.0	5.2	0.8	-4.4	-2.8
	SD	49.99	10.67	51.27	16.09	37.41	44.47	34.63	30.40
	Min	-24.0	-27.0	-30.0	-35.0	-43.0	-30.0	-122.0	-122.0
	Median	-7.0	-6.0	0.5	-22.0	-4.0	-18.0	-4.5	-4.0
	Max	121.0	7.0	84.0	-3.0	44.0	79.0	60.0	54.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

24 HOUR URINE: Urine Creatinine-QT (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	5	1	4	5	3	27	42
	Mean	24.0	0.0	-23.0	4.5	-7.2	-10.7	6.1	1.4
	SD	25.46	34.48	.	40.93	20.02	21.46	37.52	34.55
	Min	6.0	-37.0	-23.0	-52.0	-32.0	-25.0	-62.0	-62.0
	Median	24.0	0.0	-23.0	12.0	-8.0	-21.0	2.0	-1.0
	Max	42.0	53.0	-23.0	46.0	22.0	14.0	97.0	97.0
GL701 100mg									
	Number	8	8	7	4	6	6	23	43
	Mean	1.6	2.6	2.0	22.5	14.5	22.5	-4.8	1.8
	SD	55.74	25.30	13.82	31.68	36.18	19.21	61.87	51.26
	Min	-82.0	-26.0	-16.0	-18.0	-22.0	4.0	-217.0	-217.0
	Median	18.0	-2.0	-2.0	25.0	5.0	18.0	5.0	6.0
	Max	61.0	52.0	29.0	58.0	84.0	51.0	112.0	112.0
GL701 200mg									
	Number	9	9	5	5	5	5	25	40
	Mean	-10.0	-11.7	3.8	6.0	14.0	-9.0	9.7	2.8
	SD	25.64	27.33	26.84	16.63	36.80	54.30	45.99	45.01
	Min	-65.0	-65.0	-38.0	-8.0	-27.0	-74.0	-121.0	-121.0
	Median	-9.0	4.0	10.0	1.0	1.0	9.0	6.0	0.0
	Max	28.0	19.0	30.0	34.0	71.0	44.0	129.0	129.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

24 HOUR URINE: Serum Creat-Urine Chem.-QT (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	4	1	4	5	3	26	41
	Mean	-0.1	-0.1	0.5	0.2	0.0	0.0	-0.0	-0.0
	SD	0.14	0.06	.	0.32	0.05	0.10	0.12	0.13
	Min	-0.2	-0.1	0.5	-0.1	0.0	-0.1	-0.3	-0.3
	Median	-0.1	-0.1	0.5	0.3	0.0	0.0	0.0	0.0
	Max	0.0	0.0	0.5	0.5	0.1	0.1	0.2	0.5
GL701 100mg									
	Number	5	6	4	3	6	6	19	38
	Mean	0.1	0.2	-0.0	0.2	0.1	0.0	0.1	0.1
	SD	0.19	0.48	0.24	0.15	0.23	0.09	0.36	0.28
	Min	-0.1	-0.2	-0.3	0.0	-0.1	-0.1	-0.2	-0.3
	Median	0.1	0.1	0.0	0.2	0.1	0.0	0.0	0.0
	Max	0.4	1.1	0.3	0.3	0.5	0.1	1.4	1.4
GL701 200mg									
	Number	7	7	4	3	5	5	24	37
	Mean	0.1	0.0	0.2	0.3	0.2	0.1	0.1	0.1
	SD	0.09	0.05	0.14	0.17	0.49	0.22	0.14	0.15
	Min	0.0	0.0	0.1	0.1	-0.1	0.0	-0.2	-0.2
	Median	0.1	0.0	0.2	0.4	0.1	0.0	0.1	0.1
	Max	0.2	0.1	0.4	0.4	1.1	0.5	0.3	0.5

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

24 HOUR URINE: Urine Total Protein (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	8	11	9	10	11	7	38	56
	Mean	71.7	-2.2	-9.9	13.2	30.3	33.2	9.8	3.7
	SD	142.90	40.60	33.40	27.83	58.39	70.34	33.83	32.32
	Min	-6.8	-86.9	-96.0	-8.5	-19.6	-28.2	-21.1	-96.0
	Median	-0.3	0.0	-2.2	2.7	8.8	10.2	0.6	0.0
	Max	405.2	78.7	19.0	85.2	167.0	178.0	165.4	165.4
GL701 100mg									
	Number	16	14	14	16	14	14	32	52
	Mean	28.8	36.6	13.3	8.0	28.0	22.5	-4.3	18.2
	SD	145.81	111.58	160.03	76.42	88.03	85.78	39.60	80.87
	Min	-75.8	-133.9	-183.4	-159.6	-168.6	-173.5	-196.8	-196.8
	Median	0.1	23.8	2.3	15.1	13.2	6.7	-0.8	3.4
	Max	560.9	359.7	486.9	152.4	182.5	172.7	84.1	486.9
GL701 200mg									
	Number	17	11	12	9	11	17	33	53
	Mean	39.7	14.2	41.8	59.8	95.0	72.5	27.1	34.2
	SD	122.62	26.10	53.01	70.98	129.51	119.57	104.24	107.39
	Min	-13.0	-11.0	-13.2	-23.6	-11.7	-7.4	-18.1	-18.1
	Median	-0.2	9.2	43.9	26.4	19.5	15.0	4.3	4.3
	Max	481.8	61.7	155.2	170.2	347.2	364.0	521.1	521.1

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

24 HOUR URINE: 24h Urine Protein (mg/day)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	8	11	9	10	11	7	38	56
	Mean	692.6	-212.3	-235.4	180.6	359.3	633.9	133.9	34.0
	SD	1192.42	639.37	670.42	495.97	994.05	1693.51	628.89	598.66
	Min	-323.0	-1885.0	-1920.0	-292.0	-431.0	-670.0	-273.0	-1920.0
	Median	64.5	-190.0	-141.0	80.5	51.0	91.0	29.0	20.0
	Max	2631.0	767.0	395.0	1343.0	3230.0	4391.0	3740.0	3740.0
GL701 100mg									
	Number	16	14	14	16	14	14	32	52
	Mean	288.5	391.4	135.1	-35.3	190.9	248.2	-10.5	323.5
	SD	1626.99	2242.69	2230.51	1614.14	1593.72	1496.25	866.51	1303.28
	Min	-1406.0	-2505.0	-3219.0	-3012.0	-3126.0	-3067.0	-3530.0	-3530.0
	Median	12.5	99.0	8.5	81.0	59.5	100.0	61.5	61.5
	Max	5914.0	7250.0	6215.0	3021.0	3239.0	2596.0	2599.0	6215.0
GL701 200mg									
	Number	17	11	12	9	11	17	33	53
	Mean	1246.4	91.7	229.8	502.1	802.0	1401.8	419.2	870.5
	SD	5242.16	703.28	1634.34	923.50	1545.53	2535.81	1608.34	3285.71
	Min	-1610.0	-1385.0	-3978.0	-168.0	-337.0	-99.0	-300.0	-300.0
	Median	21.0	37.0	105.5	129.0	381.0	212.0	36.0	51.0
	Max	21491.0	1638.0	2704.0	2683.0	5190.0	8263.0	7801.0	21491.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

LIPID GROUP: Cholesterol (High Performance) (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	3	2	2	4	1	46	61
	Mean	3.5	-18.3	-29.0	-10.0	-48.5	-21.0	-19.5	-19.6
	SD	7.78	10.79	26.87	2.83	88.66	.	41.26	42.64
	Min	-2.0	-26.0	-48.0	-12.0	-181.0	-21.0	-79.0	-181.0
	Median	3.5	-23.0	-29.0	-10.0	-9.5	-21.0	-22.0	-19.0
	Max	9.0	-6.0	-10.0	-8.0	6.0	-21.0	193.0	193.0
GL701 100mg									
	Number	1	1	4	2	1	4	43	61
	Mean	-16.0	41.0	23.5	38.5	-17.0	6.8	-22.7	-13.3
	SD	.	.	22.43	20.51	.	23.77	30.91	39.70
	Min	-16.0	41.0	-1.0	24.0	-17.0	-22.0	-112.0	-112.0
	Median	-16.0	41.0	25.5	38.5	-17.0	9.5	-23.0	-18.0
	Max	-16.0	41.0	44.0	53.0	-17.0	30.0	37.0	138.0
GL701 200mg									
	Number	2	3	1	1	3	5	40	57
	Mean	44.5	-4.3	-44.0	-51.0	-36.7	20.6	-27.0	-20.5
	SD	84.15	17.67	.	.	36.68	77.66	53.52	54.73
	Min	-15.0	-16.0	-44.0	-51.0	-78.0	-25.0	-111.0	-111.0
	Median	44.5	-13.0	-44.0	-51.0	-24.0	-15.0	-36.5	-26.0
	Max	104.0	16.0	-44.0	-51.0	-8.0	157.0	219.0	219.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

LIPID GROUP: LDL-Chol. Revised-Delong (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	3	2	2	3	1	46	60
	Mean	2.0	-13.3	-29.5	-8.5	-3.7	-11.0	-12.5	-11.4
	SD	14.14	9.07	14.85	12.02	4.04	.	31.34	28.30
	Min	-8.0	-20.0	-40.0	-17.0	-8.0	-11.0	-50.0	-50.0
	Median	2.0	-17.0	-29.5	-8.5	-3.0	-11.0	-17.5	-15.5
	Max	12.0	-3.0	-19.0	0.0	0.0	-11.0	152.0	152.0
GL701 100mg									
	Number	1	1	4	2	1	4	43	61
	Mean	-8.0	55.0	9.5	23.5	63.0	12.0	-9.0	-1.8
	SD	.	.	19.33	31.82	.	26.01	24.92	31.21
	Min	-8.0	55.0	-12.0	1.0	63.0	-12.0	-79.0	-79.0
	Median	-8.0	55.0	7.5	23.5	63.0	12.5	-12.0	-9.0
	Max	-8.0	55.0	35.0	46.0	63.0	35.0	40.0	109.0
GL701 200mg									
	Number	2	3	1	1	2	5	39	55
	Mean	52.5	5.7	-42.0	-57.0	-29.0	32.4	-14.2	-8.3
	SD	79.90	4.16	.	.	41.01	86.03	29.12	41.09
	Min	-4.0	1.0	-42.0	-57.0	-58.0	-17.0	-84.0	-84.0
	Median	52.5	7.0	-42.0	-57.0	-29.0	-5.0	-15.0	-12.0
	Max	109.0	9.0	-42.0	-57.0	0.0	185.0	50.0	185.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

LIPID GROUP: HDL Cholesterol Dex Sul-Mg (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	3	2	2	3	1	46	60
	Mean	-1.5	-3.0	3.0	-2.0	-2.3	-3.0	-7.4	-6.0
	SD	0.71	1.73	7.07	4.24	5.77	.	12.86	11.78
	Min	-2.0	-4.0	-2.0	-5.0	-9.0	-3.0	-54.0	-54.0
	Median	-1.5	-4.0	3.0	-2.0	1.0	-3.0	-8.0	-4.5
	Max	-1.0	-1.0	8.0	1.0	1.0	-3.0	25.0	25.0
GL701 100mg									
	Number	1	1	4	2	1	4	43	61
	Mean	-5.0	-16.0	16.8	7.5	-65.0	-3.0	-9.5	-8.2
	SD	.	.	16.98	2.12	.	8.98	10.17	14.80
	Min	-5.0	-16.0	5.0	6.0	-65.0	-9.0	-33.0	-65.0
	Median	-5.0	-16.0	10.5	7.5	-65.0	-6.5	-10.0	-9.0
	Max	-5.0	-16.0	41.0	9.0	-65.0	10.0	10.0	41.0
GL701 200mg									
	Number	2	3	1	1	2	5	40	56
	Mean	-11.0	-4.0	-9.0	-31.0	-5.0	-7.0	-14.6	-13.5
	SD	31.11	14.42	.	.	7.07	7.18	11.72	11.80
	Min	-33.0	-16.0	-9.0	-31.0	-10.0	-14.0	-34.0	-34.0
	Median	-11.0	-8.0	-9.0	-31.0	-5.0	-9.0	-13.0	-12.5
	Max	11.0	12.0	-9.0	-31.0	0.0	2.0	18.0	18.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

LIPID GROUP: Triglycerides (GPO) (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	3	2	2	4	1	46	61
	Mean	17.0	-11.3	-16.0	4.0	-22.3	-41.0	2.9	1.5
	SD	46.67	31.82	31.11	86.27	91.45	.	53.72	53.85
	Min	-16.0	-48.0	-38.0	-57.0	-114.0	-41.0	-102.0	-114.0
	Median	17.0	5.0	-16.0	4.0	-25.0	-41.0	7.0	6.0
	Max	50.0	9.0	6.0	65.0	75.0	-41.0	183.0	183.0
GL701 100mg									
	Number	1	1	4	2	1	4	43	61
	Mean	-14.0	12.0	-16.3	49.0	-92.0	-13.8	-26.7	-20.0
	SD	.	.	30.78	80.61	.	10.40	63.48	60.10
	Min	-14.0	12.0	-45.0	-8.0	-92.0	-23.0	-169.0	-169.0
	Median	-14.0	12.0	-23.5	49.0	-92.0	-15.0	-25.0	-21.0
	Max	-14.0	12.0	27.0	106.0	-92.0	-2.0	198.0	198.0
GL701 200mg									
	Number	2	3	1	1	3	5	40	57
	Mean	18.5	-37.7	45.0	233.0	-40.7	-30.8	-4.2	-2.2
	SD	219.91	62.31	.	.	73.33	56.94	157.84	141.05
	Min	-137.0	-106.0	45.0	233.0	-124.0	-94.0	-159.0	-159.0
	Median	18.5	-23.0	45.0	233.0	-12.0	-3.0	-25.5	-19.0
	Max	174.0	16.0	45.0	233.0	14.0	27.0	894.0	894.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

LIPID GROUP: LDL/HDL Ratio

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	3	2	2	3	1	46	60
	Mean	0.0	-0.1	-0.7	-0.1	-0.1	-0.1	0.1	0.0
	SD	0.15	0.29	0.20	0.04	0.23	.	0.62	0.58
	Min	-0.1	-0.4	-0.9	-0.2	-0.3	-0.1	-1.3	-1.3
	Median	0.0	-0.1	-0.7	-0.1	-0.1	-0.1	-0.0	-0.1
	Max	0.1	0.2	-0.6	-0.1	0.2	-0.1	1.8	1.8
GL701 100mg									
	Number	1	1	4	2	1	4	43	61
	Mean	0.3	5.2	-0.6	0.1	6.5	0.5	0.5	0.6
	SD	.	.	0.79	0.55	.	1.46	0.91	1.34
	Min	0.3	5.2	-1.4	-0.3	6.5	-1.7	-1.4	-1.7
	Median	0.3	5.2	-0.6	0.1	6.5	1.2	0.5	0.5
	Max	0.3	5.2	0.3	0.5	6.5	1.3	4.8	6.5
GL701 200mg									
	Number	2	3	1	1	2	5	39	55
	Mean	3.8	0.1	-0.4	2.3	-0.3	2.3	0.5	0.8
	SD	5.68	0.67	.	.	1.35	4.66	0.85	1.87
	Min	-0.2	-0.7	-0.4	2.3	-1.3	-0.3	-1.6	-1.6
	Median	3.8	0.3	-0.4	2.3	-0.3	0.3	0.5	0.5
	Max	7.8	0.6	-0.4	2.3	0.6	10.6	2.7	10.6

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

LIPID GROUP: Total Cholesterol/HDL Ratio

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	3	2	2	3	1	46	60
	Mean	0.1	-0.1	-0.8	-0.1	-0.0	-0.2	0.2	0.1
	SD	0.03	0.42	0.24	0.31	0.35	.	0.75	0.70
	Min	0.1	-0.6	-1.0	-0.3	-0.4	-0.2	-1.3	-1.3
	Median	0.1	-0.1	-0.8	-0.1	0.0	-0.2	0.1	0.1
	Max	0.1	0.3	-0.7	0.1	0.3	-0.2	2.3	2.3
GL701 100mg									
	Number	1	1	4	2	1	4	43	61
	Mean	0.3	5.8	-0.8	0.1	6.9	0.5	0.5	0.7
	SD	.	.	1.01	0.25	.	1.74	1.02	1.50
	Min	0.3	5.8	-2.0	-0.0	6.9	-2.1	-1.6	-2.1
	Median	0.3	5.8	-0.7	0.1	6.9	1.3	0.5	0.5
	Max	0.3	5.8	0.4	0.3	6.9	1.5	5.6	6.9
GL701 200mg									
	Number	2	3	1	1	2	5	40	56
	Mean	4.7	-0.0	-0.1	5.2	-0.5	2.3	0.8	1.1
	SD	7.38	0.62	.	.	1.75	4.73	2.12	2.64
	Min	-0.5	-0.7	-0.1	5.2	-1.7	-0.5	-2.1	-2.1
	Median	4.7	0.3	-0.1	5.2	-0.5	0.3	0.5	0.5
	Max	9.9	0.4	-0.1	5.2	0.8	10.8	12.2	12.2

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

COMPLEMENT LEVELS: Complement C3-QT (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	61	61	58	55	53	49	48	63
	Mean	0.4	-0.3	-4.0	-4.3	-2.1	-1.8	-3.0	-2.7
	SD	14.03	16.59	14.71	14.03	16.33	17.68	16.69	16.11
	Min	-46.0	-43.0	-41.0	-48.0	-29.0	-39.0	-42.0	-42.0
	Median	-1.0	-1.0	-6.0	-5.0	-3.0	-2.0	-2.0	-1.0
	Max	25.0	60.0	29.0	33.0	47.0	46.0	41.0	41.0
GL701 100mg									
	Number	61	62	60	56	51	51	47	63
	Mean	-4.4	-5.9	-7.5	-8.9	-5.5	-9.2	-8.9	-8.8
	SD	23.38	21.27	18.25	16.89	13.21	18.89	19.81	20.08
	Min	-127.0	-109.0	-104.0	-101.0	-48.0	-110.0	-101.0	-101.0
	Median	-3.0	-7.0	-7.0	-6.0	-7.0	-8.0	-7.0	-8.0
	Max	38.0	67.0	52.0	21.0	46.0	23.0	31.0	36.0
GL701 200mg									
	Number	62	62	59	57	56	50	43	64
	Mean	-4.2	-6.4	-4.2	-10.6	-5.2	-9.7	-9.3	-9.1
	SD	17.79	18.08	19.41	17.63	19.28	19.38	17.78	19.21
	Min	-55.0	-75.0	-82.0	-75.0	-41.0	-58.0	-63.0	-75.0
	Median	-4.5	-4.5	-3.0	-9.0	-5.5	-11.0	-8.0	-8.0
	Max	48.0	53.0	64.0	29.0	85.0	56.0	33.0	33.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

COMPLEMENT LEVELS: Complement C4-QT (mg/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	61	61	58	55	53	49	48	63
	Mean	0.2	0.1	-1.2	-0.9	-0.2	-0.7	-1.0	-0.8
	SD	3.85	4.04	3.51	3.09	3.96	4.69	3.74	4.19
	Min	-11.0	-8.0	-12.0	-10.0	-10.0	-14.0	-9.0	-14.0
	Median	0.0	0.0	-1.0	-1.0	0.0	-1.0	-1.0	-1.0
	Max	11.0	20.0	8.0	6.0	8.0	13.0	8.0	11.0
GL701 100mg									
	Number	61	62	60	56	51	51	47	63
	Mean	-0.7	-0.8	-1.1	-1.2	-1.5	-1.5	-1.4	-1.4
	SD	5.63	5.31	3.70	3.28	3.57	3.67	3.49	5.32
	Min	-35.0	-30.0	-13.0	-11.0	-12.0	-13.0	-12.0	-30.0
	Median	0.0	0.0	0.0	-1.0	-1.0	-1.0	-1.0	0.0
	Max	12.0	16.0	12.0	6.0	8.0	7.0	7.0	12.0
GL701 200mg									
	Number	62	62	59	57	56	50	43	64
	Mean	-0.7	-1.1	-1.1	-2.5	-1.6	-3.1	-2.7	-2.2
	SD	5.56	5.91	6.42	4.68	5.21	5.21	7.07	6.36
	Min	-24.0	-23.0	-27.0	-20.0	-19.0	-24.0	-25.0	-25.0
	Median	0.0	0.0	0.0	-1.0	-0.5	-2.0	-1.0	-1.0
	Max	13.0	23.0	25.0	5.0	13.0	5.0	20.0	20.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CARDIOLIPIN LEVELS: Anti-Cardiolipin, IgG (GPL units/mL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	2	2	2	4	1	46	60
	Mean	34.4	-0.9	43.0	-1.8	6.6	0.9	2.0	4.5
	SD	43.70	0.57	29.06	3.18	12.51	.	11.57	15.67
	Min	3.5	-1.3	22.4	-4.0	-7.2	0.9	-43.2	-43.2
	Median	34.4	-0.9	43.0	-1.8	6.6	0.9	1.1	1.1
	Max	65.3	-0.5	63.5	0.5	20.5	0.9	36.1	65.3
GL701 100mg									
	Number	1	1	4	2	1	5	43	61
	Mean	0.6	-6.1	-1.7	16.1	-3.5	9.7	3.7	4.5
	SD	.	.	13.73	5.23	.	10.77	33.74	28.90
	Min	0.6	-6.1	-15.9	12.4	-3.5	-1.2	-75.0	-75.0
	Median	0.6	-6.1	-4.0	16.1	-3.5	10.5	1.1	2.4
	Max	0.6	-6.1	17.1	19.8	-3.5	22.6	195.8	195.8
GL701 200mg									
	Number	2	3	1	1	3	5	40	57
	Mean	2.9	3.5	9.4	17.9	3.5	-0.7	0.0	1.0
	SD	0.57	5.71	.	.	6.55	5.84	15.65	14.00
	Min	2.5	-2.0	9.4	17.9	-4.0	-9.0	-59.7	-59.7
	Median	2.9	3.0	9.4	17.9	6.4	2.3	2.2	2.5
	Max	3.3	9.4	9.4	17.9	8.1	4.0	34.6	34.6

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

CARDIOLIPIN LEVELS: Anti-Cardiolipin, IgM (MPL units/mL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	2	2	2	2	4	1	46	60
	Mean	0.6	3.2	0.6	-3.5	1.3	-0.2	-1.0	-0.6
	SD	1.63	5.94	4.45	3.11	2.88	.	4.21	4.05
	Min	-0.6	-1.0	-2.6	-5.7	-1.0	-0.2	-17.3	-17.3
	Median	0.6	3.2	0.6	-3.5	0.3	-0.2	-0.4	-0.2
	Max	1.7	7.4	3.7	-1.3	5.4	-0.2	12.9	12.9
GL701 100mg									
	Number	1	1	4	2	1	5	43	61
	Mean	-15.0	3.4	-4.1	-19.6	-3.8	-0.5	-1.7	-2.3
	SD	.	.	9.51	13.08	.	1.45	6.13	7.00
	Min	-15.0	3.4	-18.2	-28.8	-3.8	-1.7	-37.0	-37.0
	Median	-15.0	3.4	-0.1	-19.6	-3.8	-1.0	-0.4	-0.4
	Max	-15.0	3.4	2.1	-10.3	-3.8	2.0	4.8	4.8
GL701 200mg									
	Number	2	3	1	1	3	5	40	57
	Mean	-1.8	0.5	1.7	-101.7	0.8	0.0	-1.5	-2.8
	SD	1.27	1.30	.	.	3.84	0.45	3.85	13.77
	Min	-2.7	-0.8	1.7	-101.7	-2.5	-0.6	-10.5	-101.7
	Median	-1.8	0.4	1.7	-101.7	-0.2	0.0	-0.8	-0.6
	Max	-0.9	1.8	1.7	-101.7	5.0	0.6	5.8	5.8

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

OTHER: Anti-Double Stranded DNA (IU/mL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	61	61	59	55	53	49	48	63
	Mean	21.6	30.4	44.0	41.0	25.4	32.9	15.7	33.4
	SD	191.79	184.56	258.32	186.37	146.70	158.72	59.91	166.32
	Min	-113.5	-100.0	-24.7	-14.3	-23.0	-60.6	-10.5	-10.5
	Median	0.0	0.0	0.0	0.1	0.0	0.0	0.2	0.2
	Max	1487.7	1366.9	1973.9	1264.9	1055.5	1013.5	380.3	1264.9
GL701 100mg									
	Number	61	62	60	56	51	50	47	63
	Mean	-29.1	26.0	21.2	56.2	28.3	15.2	8.7	30.3
	SD	320.34	174.69	174.40	227.81	146.37	49.87	81.28	145.50
	Min	-2442.6	-327.0	-593.2	-25.1	-16.7	-29.4	-295.0	-295.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	410.0	1147.7	888.1	1333.0	1043.5	294.0	442.5	858.9
GL701 200mg									
	Number	62	63	59	57	56	50	43	64
	Mean	-21.9	-27.6	-31.8	-24.0	-27.0	-22.5	-29.7	-6.2
	SD	152.89	152.17	158.36	163.88	168.95	176.67	187.78	186.12
	Min	-1196.1	-1197.7	-1206.1	-1201.5	-1206.0	-1204.6	-1209.4	-1209.4
	Median	0.0	-0.2	-0.4	0.0	0.0	0.0	0.0	0.0
	Max	86.0	61.8	4.3	195.8	270.5	162.9	90.6	832.7

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

OTHER: Estradiol- Double Antibody (pg/mL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	1	3	2	2	3	1	46	59
	Mean	116.5	6.3	-60.9	-39.1	-18.2	260.9	16.9	8.9
	SD	.	16.14	95.32	117.31	17.41	.	102.12	96.83
	Min	116.5	-5.8	-128.3	-122.0	-34.7	260.9	-132.5	-132.5
	Median	116.5	0.0	-60.9	-39.1	-19.8	260.9	0.0	0.0
	Max	116.5	24.6	6.5	43.9	0.0	260.9	440.3	440.3
GL701 100mg									
	Number	3	1	4	2	1	4	42	60
	Mean	17.4	-31.7	0.7	61.0	31.2	12.8	0.8	5.4
	SD	13.68	.	29.54	28.00	.	25.20	100.50	84.70
	Min	1.6	-31.7	-40.8	41.2	31.2	-6.1	-312.2	-312.2
	Median	25.3	-31.7	10.2	61.0	31.2	3.7	16.4	13.6
	Max	25.3	-31.7	23.2	80.8	31.2	49.6	254.7	254.7
GL701 200mg									
	Number	2	3	1	1	3	5	40	57
	Mean	46.0	-92.6	-316.4	-66.1	104.0	-32.8	40.7	20.0
	SD	0.00	51.25	.	.	128.59	136.56	153.83	154.98
	Min	46.0	-131.0	-316.4	-66.1	19.0	-165.8	-255.2	-316.4
	Median	46.0	-112.4	-316.4	-66.1	41.0	-12.7	42.1	33.8
	Max	46.0	-34.4	-316.4	-66.1	251.9	168.9	688.2	688.2

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

OTHER: Total Testosterone (ng/dL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	1	3	2	2	3	1	46	59
	Mean	19.0	1.7	-5.5	-7.0	-1.3	13.0	1.0	0.5
	SD	.	1.53	10.61	9.90	2.08	.	15.39	14.12
	Min	19.0	0.0	-13.0	-14.0	-3.0	13.0	-31.0	-31.0
	Median	19.0	2.0	-5.5	-7.0	-2.0	13.0	0.0	0.0
	Max	19.0	3.0	2.0	0.0	1.0	13.0	39.0	39.0
GL701 100mg									
	Number	3	1	4	2	1	4	42	60
	Mean	8.0	-2.0	17.0	2.5	10.0	20.8	26.0	22.2
	SD	19.05	.	25.26	6.36	.	30.87	39.35	35.13
	Min	-3.0	-2.0	-3.0	-2.0	10.0	-22.0	-26.0	-26.0
	Median	-3.0	-2.0	8.5	2.5	10.0	28.0	18.0	17.5
	Max	30.0	-2.0	54.0	7.0	10.0	49.0	239.0	239.0
GL701 200mg									
	Number	2	3	1	1	3	5	40	57
	Mean	3.0	-19.3	-18.0	-12.0	25.7	17.8	74.6	56.9
	SD	0.00	16.77	.	.	27.10	25.15	60.57	60.20
	Min	3.0	-30.0	-18.0	-12.0	0.0	0.0	-3.0	-30.0
	Median	3.0	-28.0	-18.0	-12.0	23.0	13.0	60.5	49.0
	Max	3.0	0.0	-18.0	-12.0	54.0	61.0	220.0	220.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

OTHER: Follicle Stiumlating Hormone (mIU/mL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visit 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	1	3	2	2	3	1	46	59
	Mean	-4.0	12.3	9.5	1.5	4.3	-4.0	2.6	3.5
	SD		10.79	14.85	7.78	6.35		18.67	17.04
	Min	-4.0	0.0	-1.0	-4.0	-3.0	-4.0	-53.0	-53.0
	Median	-4.0	17.0	9.5	1.5	8.0	-4.0	0.0	1.0
	Max	-4.0	20.0	20.0	7.0	8.0	-4.0	49.0	49.0
GL701 100mg									
	Number	3	1	4	2	1	4	42	60
	Mean	-3.0	-1.0	-6.0	-2.0	5.0	7.5	-4.0	-3.3
	SD	3.46		27.65	2.83		21.02	23.56	21.51
	Min	-7.0	-1.0	-46.0	-4.0	5.0	-4.0	-90.0	-90.0
	Median	-1.0	-1.0	4.5	-2.0	5.0	-2.5	-1.0	-1.0
	Max	-1.0	-1.0	13.0	0.0	5.0	39.0	49.0	49.0
GL701 200mg									
	Number	3	3	1	1	3	5	40	57
	Mean	11.7	1.0	4.0	-3.0	-27.3	15.0	-6.8	-5.9
	SD	2.89	8.19			38.03	31.12	27.81	28.92
	Min	10.0	-8.0	4.0	-3.0	-70.0	-5.0	-126.0	-126.0
	Median	10.0	3.0	4.0	-3.0	-15.0	3.0	1.0	1.0
	Max	15.0	8.0	4.0	-3.0	3.0	70.0	30.0	70.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

Table 13

Table 9.4.2.1-2

Summary Statistics for Change from Baseline* in Labtest Results
By Treatment Group and Visit
(All Randomized Patients)

OTHER: Luteinizing Hormone (mIU/mL)

TREATMENT GROUP		Dosing Visit 1	Dosing Visit 2	Dosing Visi 3	Dosing Visit 4	Dosing Visit 5	Dosing Visit 6	Dosing Visit 7	Last** Visit
Placebo									
	Number	1	3	2	2	3	1	46	59
	Mean	7.0	6.7	13.5	1.5	0.3	26.0	0.0	1.1
	SD		7.09	20.51	2.12	2.52		13.65	12.77
	Min	7.0	-1.0	-1.0	0.0	-2 0	26.0	-31.0	-31.0
	Median	7.0	8.0	13.5	1.5	0.0	26.0	0.0	0.0
	Max	7.0	13.0	28.0	3.0	3.0	26.0	31.0	31.0
GL701 100mg									
	Number	3	1	4	2	1	4	42	60
	Mean	3.7	0.0	-4.5	-1.5	0.0	8.8	-1.3	-0.8
	SD	4.04		5.32	0.71		9.84	16.14	14.13
	Min	-1.0	0.0	-11.0	-2.0	0.0	0.0	-50.0	-50.0
	Median	6.0	0.0	-4.5	-1.5	0.0	7.5	-0.5	0.0
	Max	6.0	0.0	2.0	-1.0	0.0	20.0	53.0	53.0
GL701 200mg									
	Number	2	3	1	1	3	5	40	57
	Mean	5.0	1.3	-3.0	-2.0	-4.3	8.0	-4.8	-3.4
	SD	0.00	2.52			8.39	12.35	20.95	19.25
	Min	5.0	-1.0	-3.0	-2.0	-14.0	-6.0	-103.0	-103.0
	Median	5.0	1.0	-3.0	-2.0	0.0	7.0	-1.0	-1.0
	Max	5.0	4.0	-3.0	-2.0	1.0	21.0	46.0	46.0

*Baseline refers to the last predose measurement.
**Last Visit refers to the last postbaseline measurement in the core study.

TABLE 16

C3 and C4 Complement (mg/dl) in SLE Patients (Study GL94-01)							
Treat-ment Group		Baseline[1]		Last Visit		Change from Baseline to Last Visit	
		C3	C4	C3	C4	C3	C4
Placebo	Number	63	63	63	63	63	63
	Mean	100.5	18.3	97.8	17.5	-2.7	-0.8
	(SD)	(27.4)	(7.4)	(29.5)	(7.0)	(16.1)	(4.2)
	Median	99.0	17.0	97.0	16.0	-1.0	-1.0
	Range	29.0/160.0	8.0/36.0	30.0/184.0	8.0/41.0	-42.0/41.0	-14.0/11.0
GL701 100 mg/day	Number	63	63	63	63	63	63
	Mean	98.2	17.5	89.4	16.1	-8.8†	-1.4
	(SD)	(33.5)	(9.5)	(31.6)	(7.2)	(20.1)	(5.3)
	Median	91.0	15.0	85.0	13.0	-8.0	0.0
	Range	38.0/198.0	8.0/56.0	28.0/157.0	8.0/34.0	-101.0/36.0	-30.0/12.0
GL701 200 mg/day	Number	64	64	64	64	64	64
	Mean	100.3	19.3	91.2	17.1	-9.1§	-2.2§§
	(SD)	(32.6)	(12.6)	(30.3)	(10.2)	(19.2)	(6.4)
	Median	95.0	15.0	89.5	14.0	-8.0	-1.0
	Range	30.0/183.0	8.0/76.0	14.0/186.0	8.0/70.0	-75.0/33.0	-25.0/20.0

[1]Baseline refers to the last pre-dose measurement.

[2]Last Visit refers to the last post-baseline measurement in the core study.

† P= 0.0660, GL701 100 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

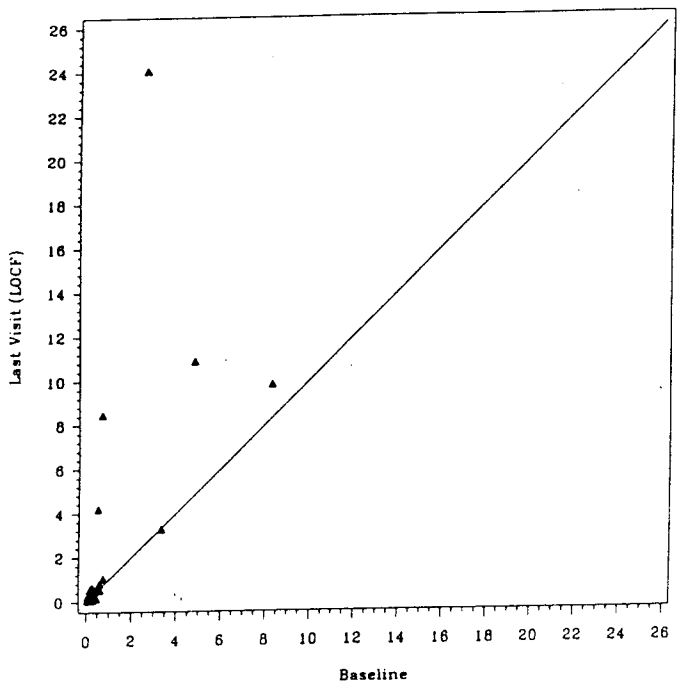
§ P= 0.0524, GL701 200 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

§§ P = 0.0300, GL701 200 mg vs. Placebo, change from baseline to last visit, one-way ANOVA.

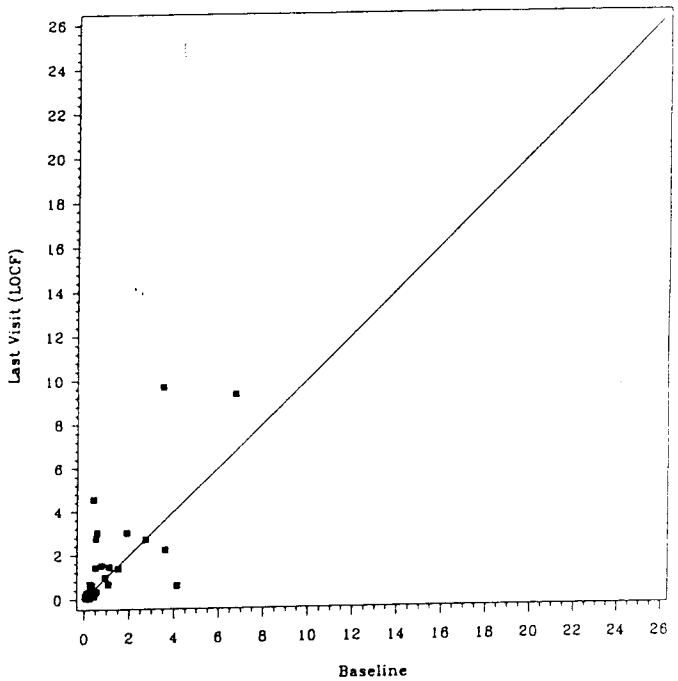
Source: Tables 9.4.2.1-1 and 2 (Tables 12 and 13)

TABLE 17

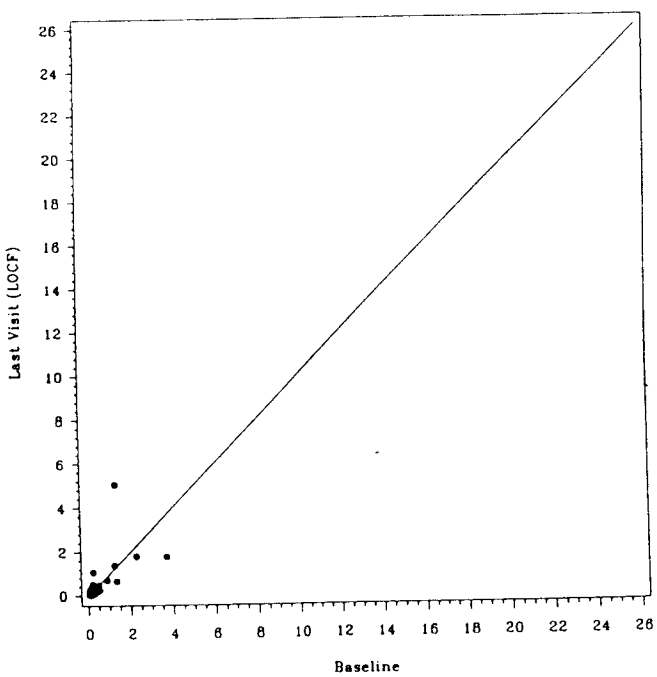
. 24H Urine Protein (g/24h)
Treatment Group: 200 mg



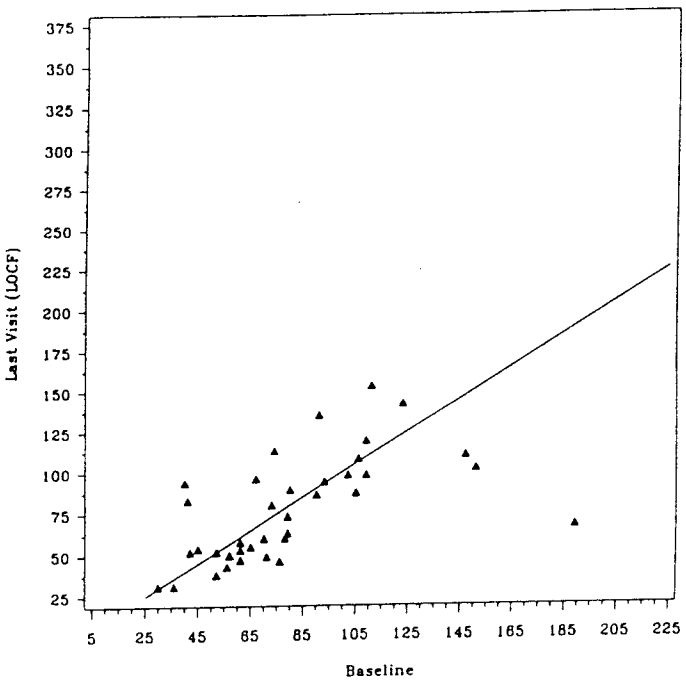
24H Urine Protein (g/24hr)
Treatment Group: 100 mg



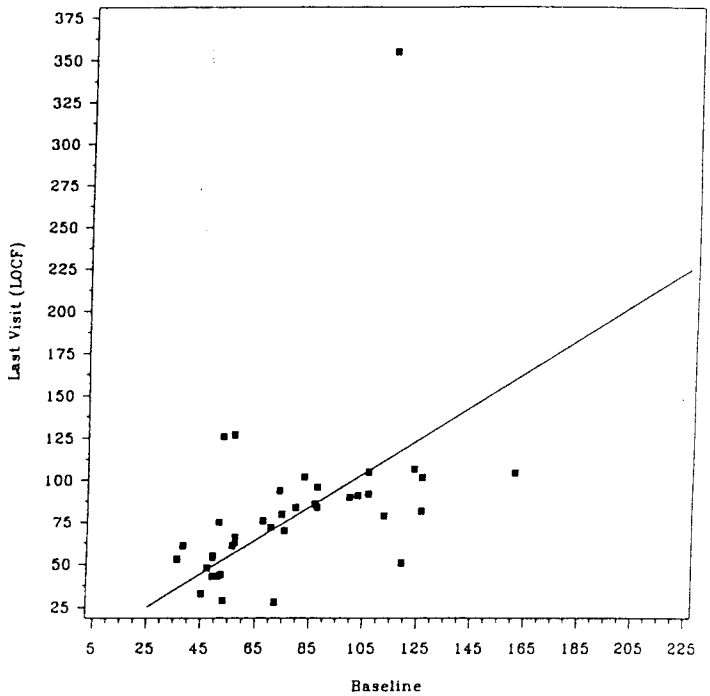
24H Urine Protein (g/24hr)
Treatment Group: Placebo



Creatinine Clearance (mL/min/1.73m2)
Treatment Group: 200 mg



Creatinine Clearance (mL/min/1.73m2)
Treatment Group: 100 mg



Creatinine Clearance (mL/min/1.73m2)
Treatment Group: Placebo

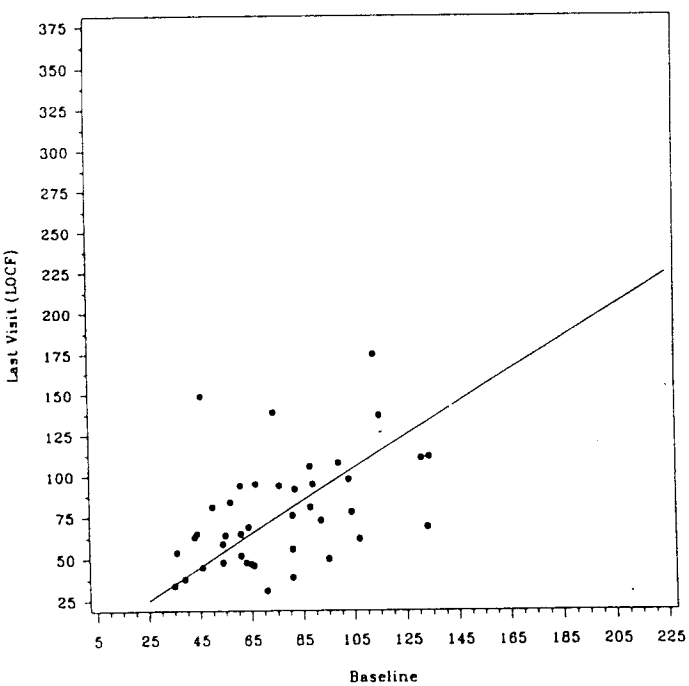


TABLE 18

B.3 Overview of Clinical Studies

Genelabs licensed from Stanford University (IND number 37,873) the rights to study GL701 in patients with SLE. Under the direction of Dr. Ronald van Vollenhoven and Dr. James McGuire, Stanford University sponsored three important studies in female patients with SLE, which helped to guide Genelabs original IND submission as well as the clinical development plan in the area of SLE. These Stanford studies, although limited by small patient numbers, provided some initial evidence that DHEA administration appeared beneficial in this patient population with mild to moderate SLE and that DHEA was well tolerated.

B.3.1 Basis for Populations Studied

In the two well-controlled studies (GL94-01 and GL95-02) and the one open label extension study (GL95-01) that support this NDA, the study population was women with active mild to moderate SLE. Approximately 90% of patients with SLE are women. It was elected not to study men in these studies for the following reasons: 1) The clinical course of SLE is different in male patients; 2) Pharmacologic doses of DHEA appear to have androgenic effects and increase levels of serum testosterone; 3) The rationale for the use of DHEA in women includes the findings that DHEA levels are lower in women with SLE and that androgens have been reported to improve SLE in women. Neither of these considerations have yet to be proven in men.

Based on the above issues, it was decided to initiate a small, blinded, placebo controlled Phase III study in men, once there was sufficient evidence of efficacy in women to justify the risk to male patients. This study, GL97-01, was initiated in February 1998 and is still ongoing.

B.3.2 GL94-01: Basis for Critical Design Features of Clinical Study

Based upon the findings of the Stanford studies, Genelabs filed an IND (No. 44,258) to study GL701 (DHEA; prasterone) under a Phase II/III controlled clinical trial protocol (GL94-01). Protocol GL94-01 [GL94-01: A Double-Blind, Randomized Phase II/III Study of GL701 in Female Patients with Mild to Moderate Systemic Lupus Erythematosus] was developed and designed based upon knowledge gained from the Stanford Studies and in collaboration with SLE experts as well as with FDA Pilot Drug Evaluation Staff (PDES). These collaboration efforts were very important to this program as there were, and still are, no general considerations and/or guidelines for conducting controlled clinical studies in SLE.

From these pre-IND / pre-protocol initiation discussions, it was decided that the endpoint or primary efficacy variable for the GL94-01 study should be a reduction of patients' current prednisone dose to a physiologic level of 7.5 mg/day or less. This reduction was to be sustained for no less than three consecutive scheduled visits, including termination visit (i.e., two consecutive months) on or after the Month 7 Visit. However, for patients to potentially achieve this prednisone reduction, it was decided that the following inclusion criteria must be followed:

- Patients with mild to moderate disease characterized by a prednisone dose of $\geq$ 10 and $\leq$ 30 mg/day and either:

  a) In the last 12 months attempted to taper prednisone dose but failed and had a stable prednisone dose for at least 6 weeks preceding the study, or

  b) Had a stable prednisone dose for at least 3 months preceding the study for those in whom there had been no attempt to taper in the last 12 months.

As noted above, patients had to have mild to moderate disease. This SLE patient population was selected over the more severe patients for the following reasons:

- Patients with severe SLE would most likely be on very high prednisone doses with poor stability.

- Patients with severe SLE would generally be on high doses of other concomitant medications, which could affect results interpretation.

- Enrollment and subsequent protocol compliance could be an issue, especially given the already small lupus population.

The doses and regimen for this study of 100 or 200 mg GL701 to be taken in the morning as a single dose were selected empirically on the basis of the previous clinical experience from the Stanford studies.

The treatment period was defined as 7 to 9 months. The 7-month period appeared to be an appropriate amount to time to identify efficacy, especially based upon the evidence of efficacy that was seen at three months in the Stanford studies. However, any patient who successfully reduced her prednisone dose to ≤ 7.5 mg/day only at the end of 6 or 7 months, would require an additional one or two months to be able to achieve the goal of two consecutive months with prednisone ≤ 7.5 mg/day. Therefore, the protocol allowed such patients to continue to receive study medication for an additional 1-2 months to evaluate whether or not this reduction could be sustained.

The GL94-01 protocol called for a sample size of 190 randomized patients to treatment. This number was determined by a standard power calculation. Additionally, with the relatively small lupus population, concerns regarding enrollment were a key limiting factor to the ultimate sample size.

B.3.3 GL95-02: Basis for Critical Design Features of Clinical Study

While study GL94-01 was on-going, plans for the initiation of a second Phase III Study, GL95-02, were under way. The intended purpose of study GL95-02 was very different from GL94-01 in that GL95-02 was developed to evaluate whether GL701 200 mg could improve disease manifestations in patients with active SLE. However, prior to the finalization of protocol GL95-02 and due to the lack of previous, large controlled clinical trials in the area of SLE, the Agency [Division of Anti-Inflammatory, Analgesic and Ophthalmic (DAIAO) Drug Products] suggested that the GL701 clinical development plan be subjected to an Advisory Committee meeting. In March 1995, a closed session meeting of the Arthritis Advisory Committee (AAC) was held to discuss some fundamental issues surrounding the GL701 clinical development program, including the design of a second Phase III clinical study. Overall, the Committee came to the consensus that study GL94-01, along with study GL95-02, would be adequate for approval of an NDA if results proved positive.

Subsequent to the AAC meeting, Genelabs and the Division went through intensive collaboration efforts to address important issues in the design of study GL95-02. These issues included employing clearly relevant tests of success, allowing

reasonable, yet evaluable concomitant treatment, and maximizing the number of evaluable patients by minimizing drop-outs.

In November 1995, Genelabs and the Division met face-to-face to further discuss the design of GL95-02 as well as initiate discussions regarding a potential New Drug Application (NDA) filing for GL701. At this meeting, Genelabs posed some questions regarding what would be clinically necessary to have a fileable and potentially approvalable NDA. Two of the more critical questions asked at that meeting, along with the Divisions answers, including comments from Dr. Janet Woodcock (CDER Director) are provided below:

1) *Would an outcome in which the primary analysis shows a trend to success (e.g., $p \leq 0.10$) with a positive result in the secondary analysis of group means ($p \leq 0.05$) be acceptable to the Agency as a positive study of therapeutic efficacy?*

Dr. Janet Woodcock answered that this is "uncharted water" and that the Agency would consider all analyses, and not just the primary end point. Dr. Michael Weintraub noted that FDA prefers by-patient analyses. Dr. Weintraub added that any trend (i.e., change in slope) toward improvement would be considered, even if the change was small.

2) *Is the proposed clinical development plan for GL701 a sufficient evaluation for an approvable NDA package, given favorable results?*

Dr. Woodcock answered that the plan was acceptable. Dr. Woodcock added that the supportive studies be completed before submission of an NDA. The planned size of the safety database would be sufficient and surpass that expected for an orphan product.

After this meeting with the Division, Genelabs was able to finalize the GL95-02 clinical protocol and initiated the study.

The key critical design feature of this protocol, which differed significantly from the design of GL94-01, was the evaluation of the effects of GL701 200 mg on disease manifestations in patients with active SLE. The primary efficacy variable for this study was the proportion of patients who are "responders." A "responder" was defined as a patient who satisfied the following conditions:

1. Improvement or stabilization in all disease activity (i.e., SLAM, SLEDAI) and constitutional symptom assessments (i.e., KFSS, Patient VAS) based on the available on-treatment data.

   For each of these four variables, the value of interest for each patient was the difference between the mean of the two baseline values and the weighted mean of all on-treatment visit measurements. Improvement or stabilization in each of SLAM, SLEDAI, KFSS, and Patient VAS was defined as the weighted mean of all on-treatment visit measurements less than or equal to the mean of the two baseline values. If, for any of SLAM, SLEDAI, KFSS, and Patient VAS, the improvement or stabilization could not be determined (i.e., either baseline or post-baseline on-treatment measurements are missing), then the rest of the available data at the on-treatment visits were used.

2. In addition, to be a responder, a patient could not have clinical deterioration. Clinical deterioration could occur as a result of serious new or progressive lupus-related conditions or requirement for unacceptable increase in immunosuppressive or cytotoxic therapy for lupus while the patient receives study drug.

The proportion of responders was decided as the primary efficacy variable because a per patient endpoint was considered desirable. The responder definition was created, with significant input from the Agency, to incorporate measures of SLE disease activity assessed by the investigator (SLEDAI and SLAM); measures of constitutional symptoms assessed by the patient (Patient VAS and KFSS); and progression of SLE or SLE-treatment related toxicity to serious morbidity ("clinical deterioration"). This responder definition was developed because there is no well established or validated per patient endpoint in SLE.

This study was designed as a double-blind, randomized placebo-controlled because many of the manifestations of SLE require subjective evaluations by either the patients or investigator. One of the important eligibility criteria was that patients have active, but relatively stable disease. To accomplish this, patients were required to have a SLAM score of ≥ 7 and had to be receiving stable doses of medications of prednisone, immunosuppressives, cytotoxics and anti-malarials; and maximum corticosteroid dose at baseline had to be ≤ 10 mg/day of prednisone or its equivalent and unchanged for ≥ 6 weeks prior to study entry. However, active SLE was further defined by protocol amendment in August, 1997 as baseline SLEDAI > 2. This criterion was added because patients with baseline SLEDAI scores of ≤ 2 (i.e., no or

little disease activity) were identified as likely to respond differently that patients with baseline SLEDAI scores of > 2 (i.e., patients with mild to moderate disease activity). This became a concern when data analyses from study GL94-01 revealed a difference in these patient populations. The Agency agreed with this amendment and at least an additional 50 patients were enrolled meeting this criterion.

This study was a 12-month study, which was chosen based upon feedback received at the AAC meeting in March 1995, when some study design elements were briefly discussed. The daily dose of 200 mg/day GL701 was selected on the basis of the results from the Stanford studies, which demonstrated 200 mg/day GL701 to be safe and effective.

Since there was no prior information regarding responder rates, the original, but later amended, sample size of 300 randomized patients was not based on statistical calculations.

Lastly, an additional per patient endpoint, time to first definite flare, was proposed as while study GL95-02 was on-going. This additional endpoint was agreed to by the Agency and added to the analysis plan under IND amendments. Although there is no accepted definition of flare, lupus flare is recognized clinically as an important event, frequently requiring modification of existing treatment. Additionally, flare, like responder, is a per-patient endpoint. In addition, flares are usually defined clinically, without reference to lupus scoring instruments, and so may be an efficacy measure independent from these instruments. Since physician or investigator instituted increases in SLE medications were part of the definition of definite flare, unlike responder, increases in prednisone or immunosuppressive would have less of a confounding effect on flare than on responder. However, because there was no widely accepted definition of flare and no previous experience in patients with mild to moderate SLE with this definition of flare, there was also concern that the number of patients with definite flares might be insufficient to provide sufficient statistical power.

B.3.4 GL97-01 (on-going): Basis for Critical Design Features of Clinical Study

As stated above, a small placebo controlled Phase III study in men was initiated in February 1998. This study was not initiated until much later in the clinical development of GL701 for SLE because of the potential risks associated with DHEA administration to men. However, once sufficient safety and efficacy data was available in women treated with GL701, Genelabs initiated this small study.

The design of this study is similar to GL95-02 in that these patients under protocol GL97-01 are being treated with GL701 200 mg daily for 12 months. However, the studies differ in that the primary efficacy variable in this study is defined as the group means for the differences between the means for SLEDAI scores. This differs from the primary "by-patient" responder analysis in Study GL95-02 because this study, with an intended enrollment of only 20 patients per treatment arm (40 patient's total), would not be sufficiently powered to detect a treatment difference in the responder analysis. However, a secondary analysis of percent "responders" using the responder definition from Study GL95-02 is included.

B.4 Overview of Completed Controlled Studies

Genelabs has completed one Phase II/III and one Phase III controlled clinical studies with GL701 under US IND 44,258 for the treatment of SLE. These studies are entitled as follows:

- **GL94-01**: A Double-Blind, Randomized Phase II/III Study of GL701 in Female Patients with Mild to Moderate Systemic Lupus Erythematosus
- **GL95-02**: A Multicenter, Randomized, Double-Blind, Placeo Controlled Study of GL701 in Female Patients with Active Systemic Lupus Erythematosus

Genelabs has also obtained complete data, including a final study report with availability of case report forms, for a double-blind, placebo controlled study conducted in Taiwan by Genelabs Biotechnology Co., Ltd. with a slightly modified formulation of GL701 for the treatment of SLE (refer to **Table B.15**). This study is being submitted as supportive. This study is entitled as follow:

- **GBL 96-01**: A Phase III clinical trial of GL701 in the management of female systemic lupus erythematosus patients in Taiwan

Please refer to **Tables B.15** and **B.16** for a tabular summary of individual study information and location of the final study reports.

TABLE 19

DROPOUTS COMPARED WITH ALL PATIENTS
BASELINE CHARACTERISTICS

Variable	All Patients		Dropouts	
	Placebo (N=192)	GL701 (N=189)	Placebo (n=35)	GL701 (N=46)
SLEDAI	5.8	6.5	6.6	7.5
SLAM	12.0	12.2	11.9	12.5
Patient VAS	55.4	55.2	56.7	55.5
Physician VAS	30.3	30.2	29.1	31.6
Fatigue score	5.6	5.5	5.6	5.6
SF36 – Physical*	31.6	31.1	32.8	29.9
SF36 – Mental*	41.7	42.5	39.9	41.7

*Placebo N = 190, GL701 N = 187
Source: s:\genelabs\dhea\gl9502\sasfile\programs\dropcomp.sas

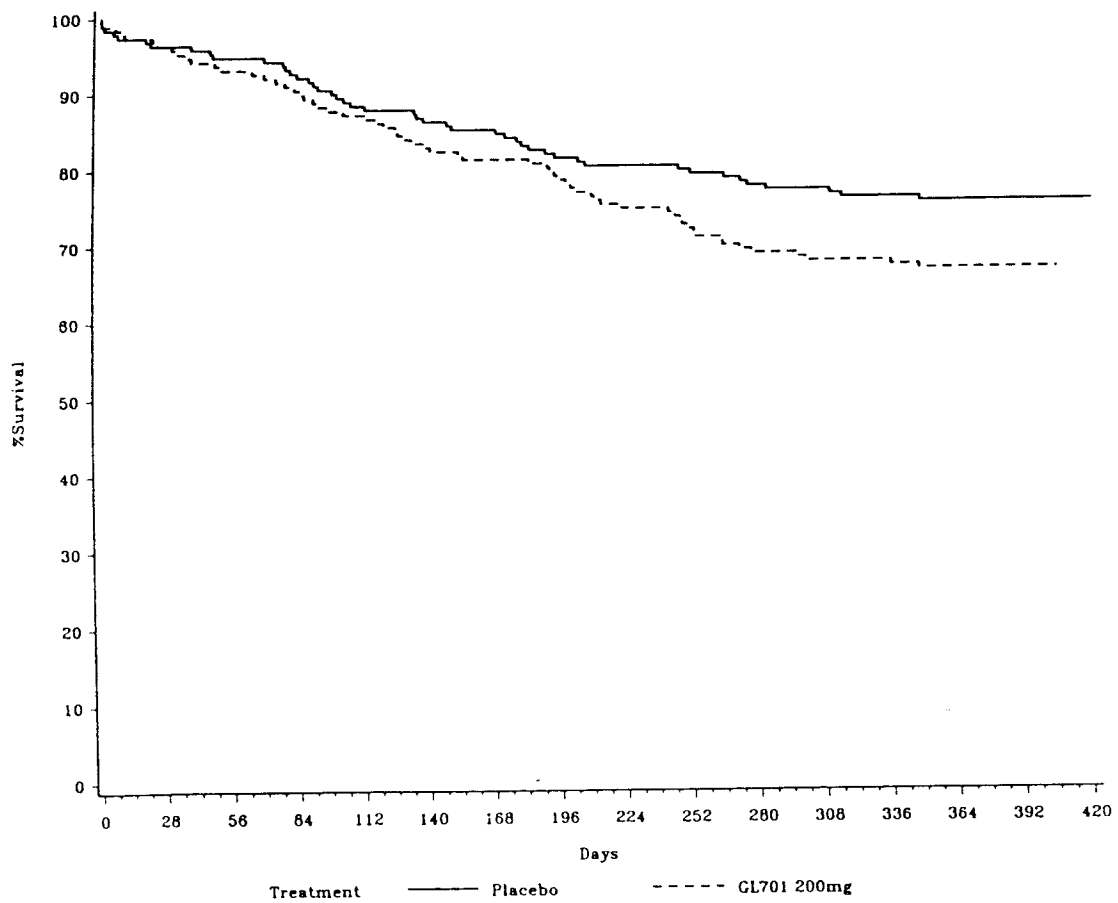
TABLE 20

D) Study GL95-02: Survival analyses for time to discontinuation for any cause

	Placebo	GL701 200mg
Discontinuation	50 (26.1%)	65 (34%)
Completion	142	124
Total	192	189
P-value (GL701 vs placebo)*	0.077	

* LR test result based on SAS PHREG Procedure

Survival Curve for Time to Early Termination of Study Medication



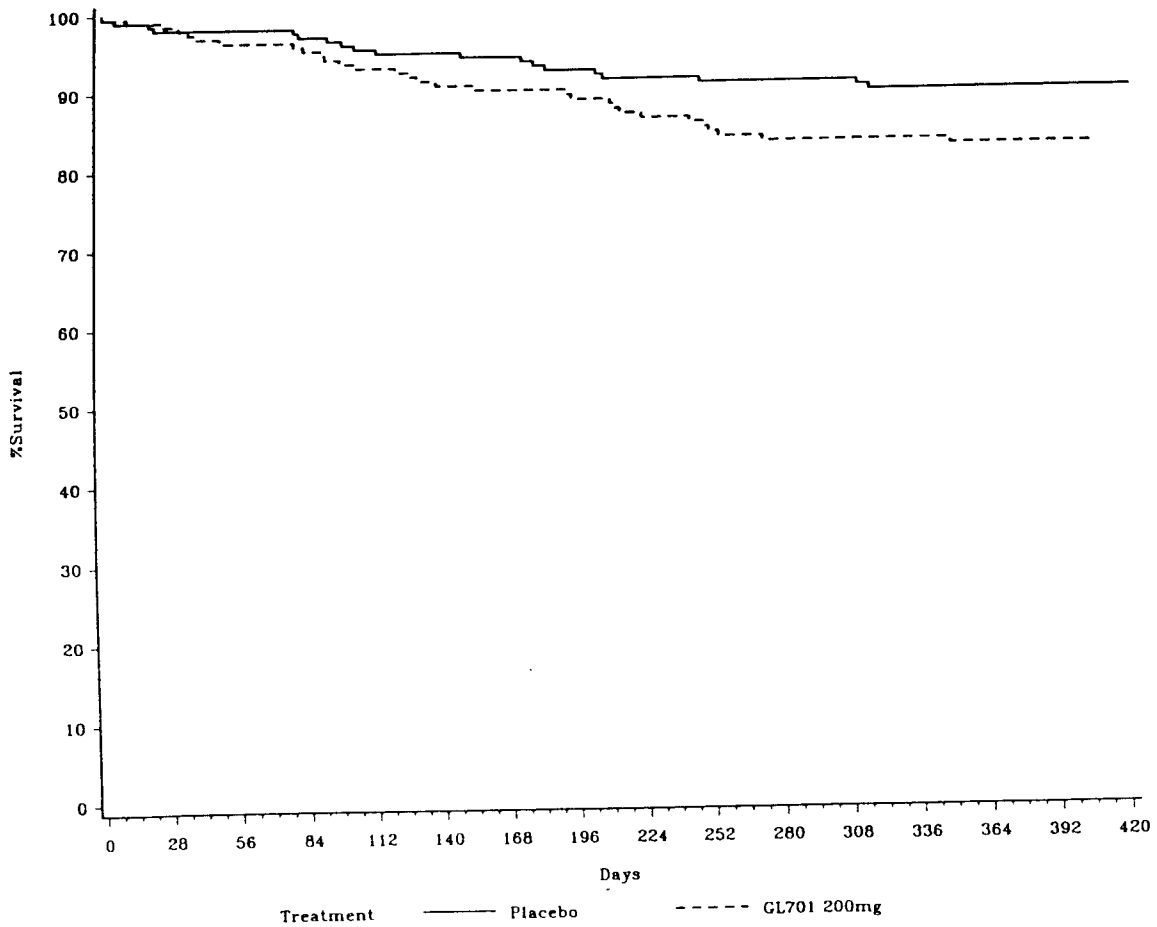
E) Study GL95-02: Survival analyses for time to discontinuation for adverse event

	Placebo	GL701 200mg
Discontinuation due to AE**	18 (9.4%)	31 (16.4%)
Completion or discontinuation due to other causes	174	158
Total	192	189
P-value (GL701 vs placebo)	0.0389	

* LR test result based on SAS PHREG Procedure

** Other events related to adverse events and deaths were included

Survival Curve for Early Termination of Study Medication due to Adverse Event



F) Study GL95-02: Survival analyses for time to discontinuation for lack of efficacy

	Placebo	GL701 200mg
Discontinuation due to lack of efficacy	9 (4.7%)	11 (5.8%)
Completion or discontinuation due to other causes	183	178
Total	192	189
P-value (GL701 vs placebo)	0.525	

• LR test result based on SAS PHREG Procedure

Survival Curve for Early Termination of Study Medication Due To Lack of Efficacy

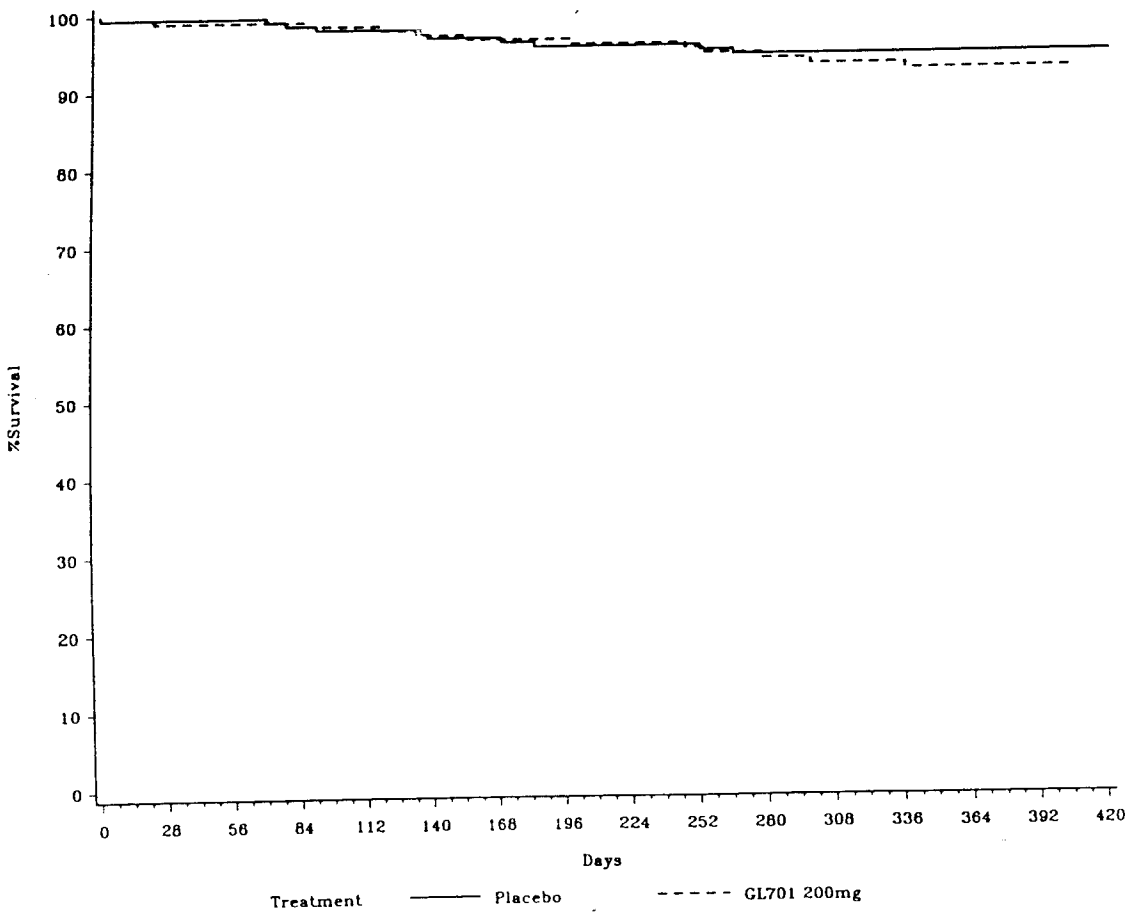


TABLE 21

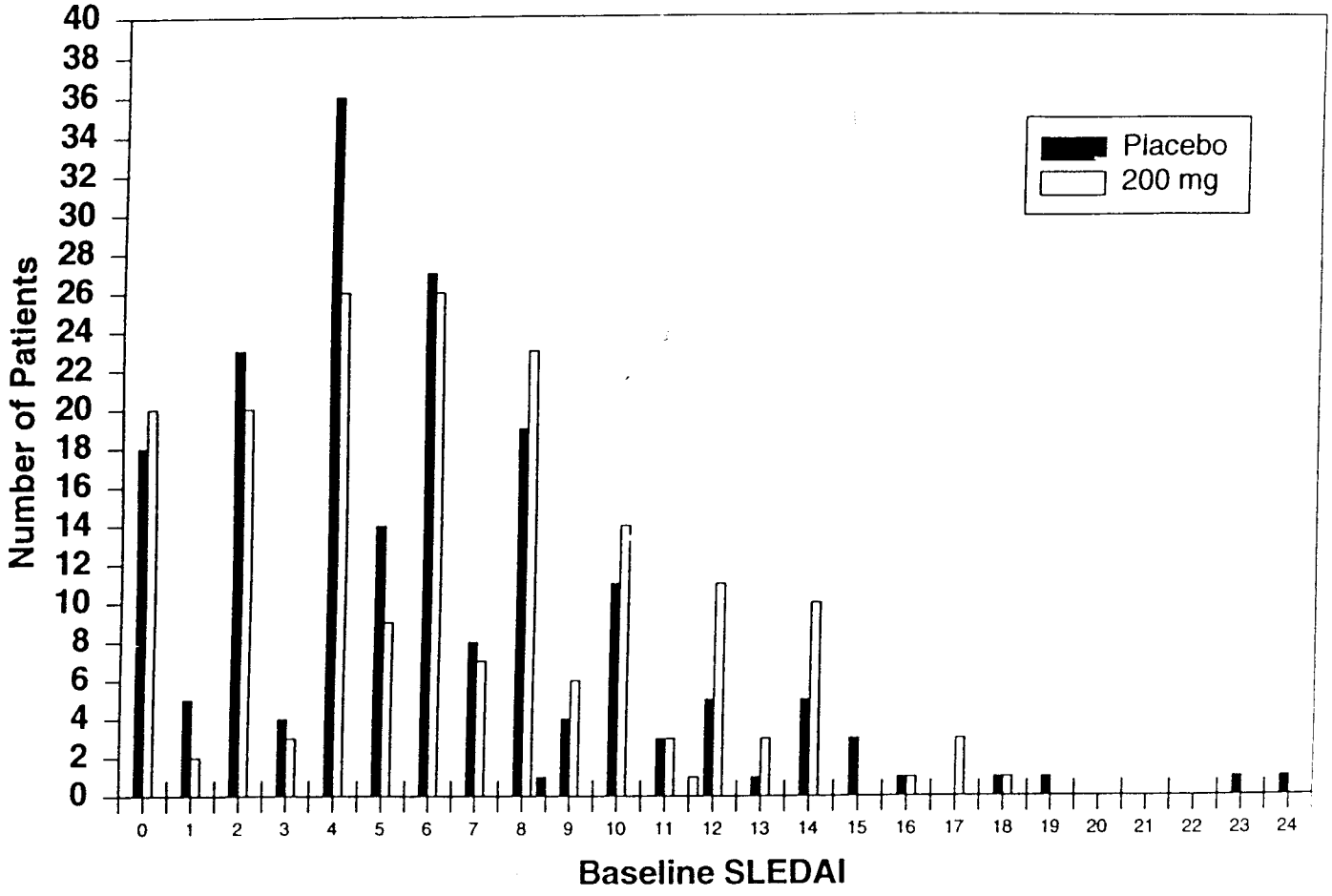
PATIENTS WITH EARLY TERMINATION DUE TO ADVERSE EVENTS

Patient	Treatment Group	Duration of Therapy (days)	Responder	Reason for Early Termination
43699	Placebo	19	no	Fatigue increased
15472	Placebo	21	no	Hot flashes
40630	Placebo	92	no	Acne, mood swings, fluid retention
38736	Placebo	98	no	Rash
3507	Placebo	103	no	Hepatitis
43602	Placebo	147	no	Weight gain
43538	Placebo	172	no	Lupus flare - skin rash
25462	Placebo	182	no	Weight gain
43614	Placebo	203	no	Suicidal depression
36638	Placebo	246	no	Pregnancy
15634	Placebo	112	yes	Pseudotumor cerebri
35710	GL701	10	no	Myalgias
15740	GL701	10	no	Depression/abdominal bloating
36513	GL701	24	no	Nausea/acne
12577	GL701	31	no	Vaginal bleeding
43616	GL701	35	no	Psychosis/delusional thoughts
20590	GL701	38	no	Nausea/bloating, foul smelling stools
36570	GL701	48	no	Weight gain
20684	GL701	78	no	Metrorrhagia
43752	GL701	82	no	Abdominal pain
25461	GL701	90	no	Depression
38403	GL701	126	no	Acne
19530	GL701	137	no	Menorrhagia
35653	GL701	213	no	Hirsutism
46695	GL701	248	no	Syncope
18670	GL701	250	no	Worsening alopecia
13761	GL701	348	no	Acne/hirsutism
43700	GL701	91	yes	Acne/hirsutism
45600	GL701	91	yes	Acne
15416	GL701	103	yes	Pulm edema.
38716	GL701	120	yes	Abdominal pain
25595	GL701	129	yes	Acne
33705	GL701	152	yes	Acne/hirsutism
18618	GL701	191	yes	Mood change/facial hair growth
3431	GL701	209	yes	Depression
43554	GL701	222	yes	Fluid retention, insomnia, leg pain, renal deterioration
38631	GL701	254	yes	Acne/hirsutism
41440	GL701	272	yes	Arthritis/hirsutism/oily skin

Source: s:\genelabs\dhea\gl9502\sasfile\extra\ks1222.sas

TABLE 22

Study GL95-02: Baseline SLEDAI by Treatment (ITT Population)



Study GL95-02: Grouped Baseline SLEDAI by Treatment (ITT Population)

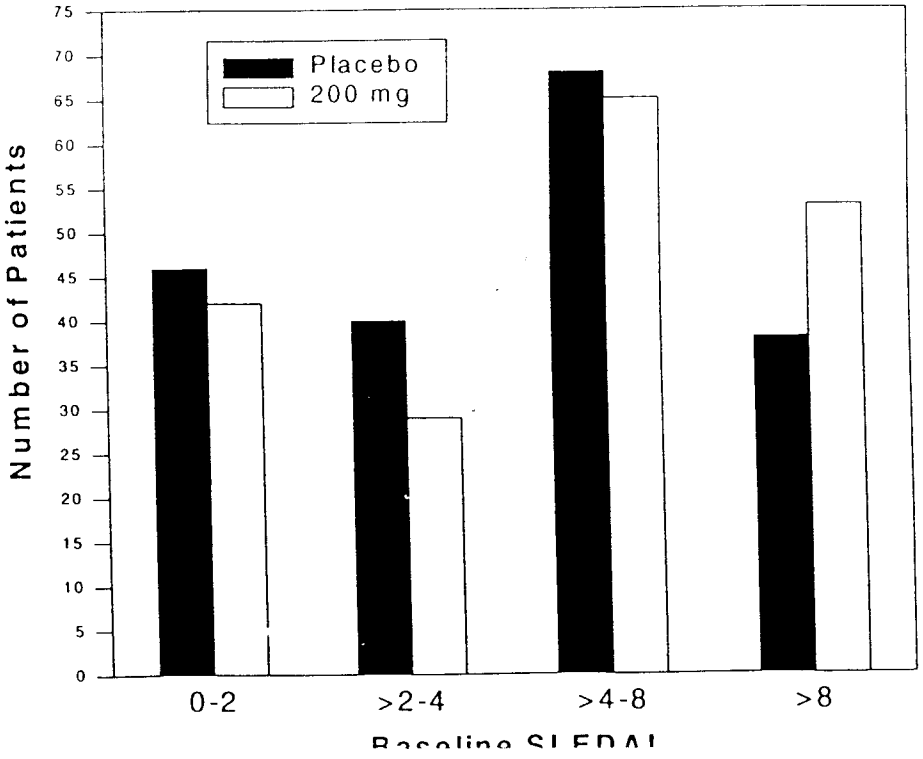
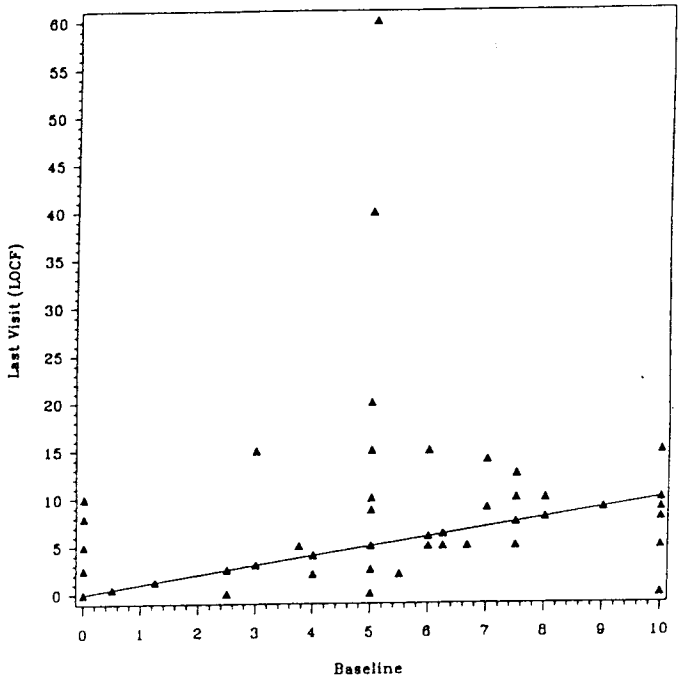


TABLE 23

Study GL95-02: Scatterplot of Actual Prednisone Dose (mg) at Baseline and Last Visit
Treatment Group: 200 mg



Study GL95-02: Scatterplot of Actual Prednisone Dose (mg) at Baseline and Last Visit
Treatment Group: Placebo

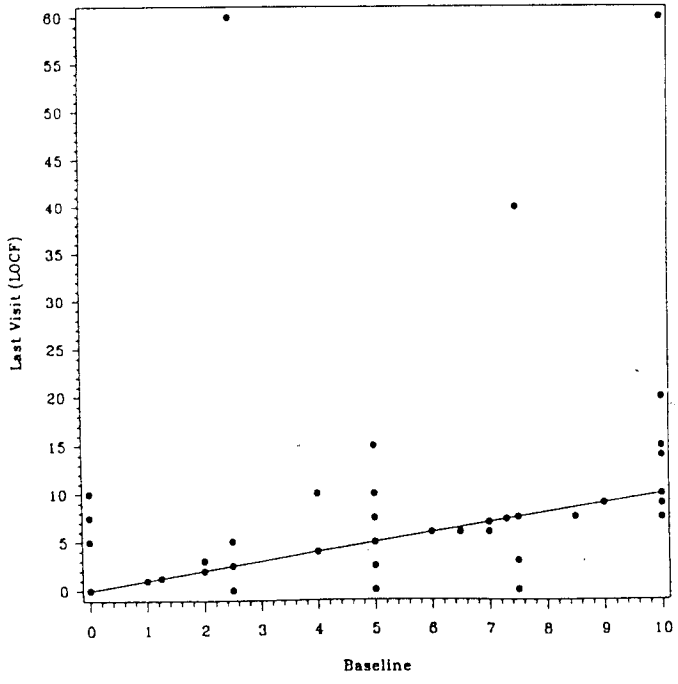


TABLE 24

Study GL95-02: Survival Analysis for Clinical Deterioration (ITT Population)

	Placebo	GL701 200 mg
Number of Patients	192	189
Number of Patients with a clinical deterioration	16 (8.3)	16 (8.5)
P-value (Placebo vs. GL701)*		0.8691

* P-value (p=0.8691) is based on a log-rank test.
Patients were followed up for 7 days after their last medication date.

Clinical Deterioration Survival Curve: (ITT Population)

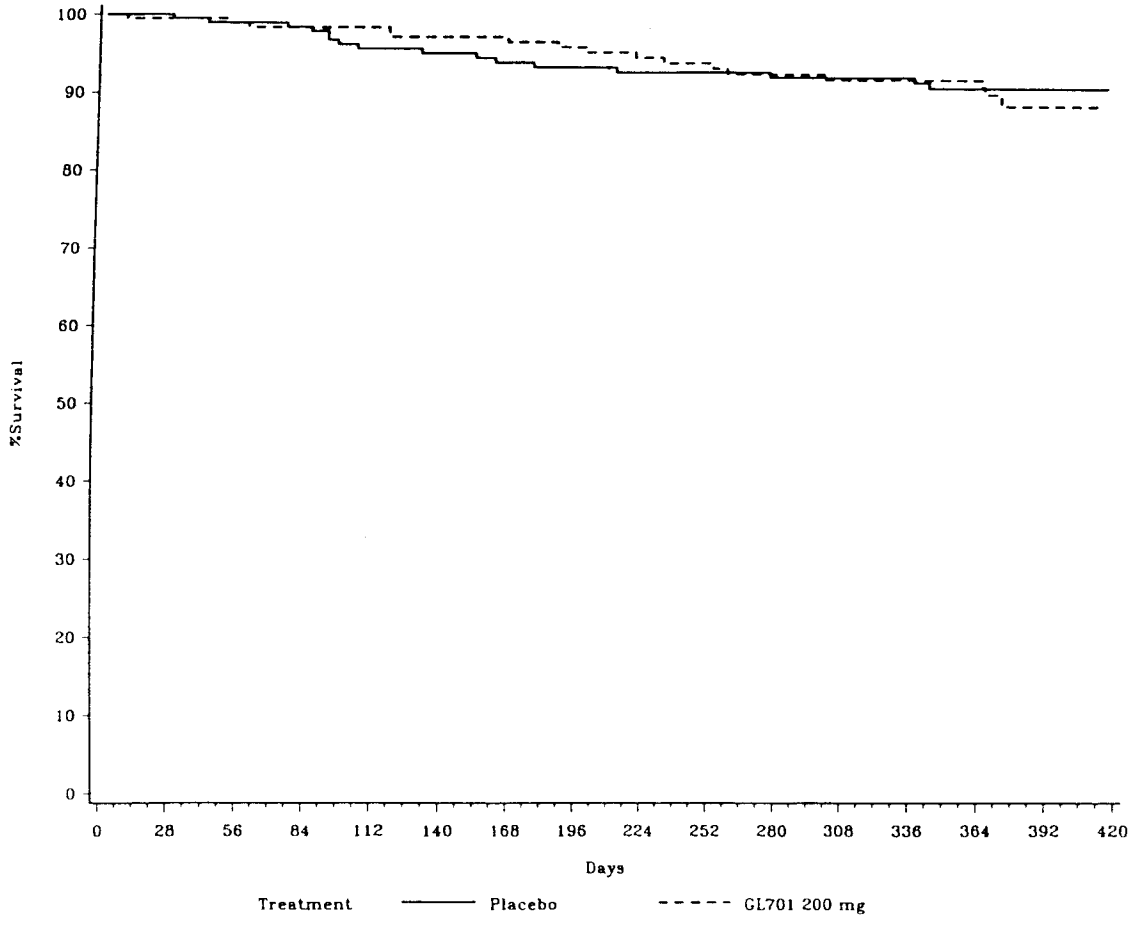


TABLE 25

ADVERSE EVENTS REPORTED BY ≥ 10% OF EITHER TREATMENT GROUP

Adverse Event	Placebo (N=192)		GL701 200 mg (N=189)	
	N	%	N	%
Rash	62	(32.3%)	75	(39.7%)
Arthralgia	71	(37.0%)	68	(36.0%)
Acne	27	(14.1%)	63	(33.3%)*
Asthenia	51	(26.6%)	45	(23.8%)
Arthritis	42	(21.9%)	45	(23.8%)
Headache	56	(29.2%)	42	(22.2%)
Myalgia	69	(35.9%)	42	(22.2%)*
Flu Syndrome	42	(21.9%)	39	(20.6%)
Hirsutism	3	(1.6%)	31	(16.4%)*
Stomatitis Ulcer	44	(22.9%)	28	(14.8%)*
Depression	30	(15.6%)	28	(14.8%)
Alopecia	39	(20.3%)	28	(14.8%)
Abdominal Pain	30	(15.6%)	27	(14.3%)
Fever	28	(14.6%)	22	(11.6%)
Vasc Dis Periph	20	(10.4%)	19	(10.1%)
Sinusitis	20	(10.4%)	17	(9.0%)
Chest Pain	20	(10.4%)	14	(7.4%)

* P<0.05, GL701 vs. placebo, Chi-Square Test
Source: s:\genelabs\dhea\gl9502\sasfile\programs\t_ae1.sas 6.12 15OCT99
Table 49: Adverse Events by Body System and COSTART

TABLE 26

ADVERSE EVENTS ASSESSED AS POSSIBLY/PROBABLY RELATED AND REPORTED BY ≥ 5% OF EITHER TREATMENT GROUP

Adverse Event	Placebo (N=192)		GL701 200 mg (N=189)	
	N	%	N	%
Acne	24	(12.5%)	61	(32.3)
Headache	10	(5.2%)	3	(1.6%)
Hirsutism	3	(1.6%)	31	(16.4%)
Depression	10	(5.2%)	10	(5.3%)
Rash	10	(5.2%)	11	(5.8%)

Patients may be reported more than once within a body system, but can occur once at most within a COSTART.
If a patient has more than one adverse event within a COSTART, the most related event to the study drug is summarized. TESS (Treatment Emergent Signs and Symptoms) is defined as those events with onset date after qualifying visit date and within 42 days after the last known study medication date.
Source: s:\genelabs\dhea\gl9502\sasfile\programs\t_ae2.sas 6.12 15OCT99
Table 50: AE by Relationship

PATIENTS WITH SEVERE ADVERSE EVENTS BY BODY SYSTEM AND COSTART

COSTART	Placebo (N=192)	GL701 200 mg (N=189)
BODY AS A WHOLE		
ALLERG REACT	0 (0.0)	1 (0.5)
ASTHENIA	18 (9.4)	15 (7.9)
CHILLS FEVER	1 (0.5)	0 (0.0)
CYST	2 (1.0)	0 (0.0)
FEVER	1 (0.5)	0 (0.0)
FLU SYND	1 (0.5)	1 (0.5)
HEADACHE	3 (1.6)	4 (2.1)
INJURY ACCID	1 (0.5)	0 (0.0)
MALAISE	1 (0.5)	0 (0.0)
PAIN	1 (0.5)	1 (0.5)
PAIN ABDO	0 (0.0)	3 (1.6)
PAIN BACK	1 (0.5)	1 (0.5)
PAIN CHEST	2 (1.0)	2 (1.1)
SUICIDE ATTEMPT	1 (0.5)	0 (0.0)
CARDIOVASCULAR		
EMB PULM	1 (0.5)	0 (0.0)
HEART ARREST	1 (0.5)	0 (0.0)
INFARCT MYOCARD	1 (0.5)	1 (0.5)
PERICARDITIS	1 (0.5)	0 (0.0)

COSTART	Placebo (N=192)	GL701 200 mg (N=189)
CARDIOVASCULAR		
VASC DIS	0 (0.0)	1 (0.5)
VASC DIS PERIPH	0 (0.0)	1 (0.5)
VASCULITIS	0 (0.0)	1 (0.5)
DIGESTION		
ESOPHAGITIS	1 (0.5)	0 (0.0)
PANCREATITIS	1 (0.5)	1 (0.5)
TOOTH DIS	1 (0.5)	0 (0.0)
HEMATOLOGIC AND LYMPHATIC		
ANEMIA	0 (0.0)	1 (0.5)
LEUKOPENIA	1 (0.5)	0 (0.0)
LYMPHOMA LIKE REACT	1 (0.5)	0 (0.0)
THROMBOCYTOPENIA	1 (0.5)	0 (0.0)
METABOLIC AND NUTRITIONAL		
ALBUMINURIA	1 (0.5)	0 (0.0)
DIABETES MELL	0 (0.0)	2 (1.1)
EDEMA	1 (0.5)	1 (0.5)
WEIGHT DEC	1 (0.5)	1 (0.5)

COSTART	Placebo (N=192)	GL701 200 mg (N=189)
MUSCULOSKELETAL		
ARTHRALGIA	2 (1.0)	3 (1.6)
ARTHRITIS	2 (1.0)	4 (2.1)
BONE FRACT SPONTAN	0 (0.0)	1 (0.5)
FIBRO TENDON	1 (0.5)	0 (0.0)
JOINT DIS	1 (0.5)	1 (0.5)
MYALGIA	5 (2.6)	1 (0.5)
MYOSITIS	1 (0.5)	0 (0.0)
OSTEOMYELITIS	1 (0.5)	0 (0.0)
TENDON DIS	0 (0.0)	1 (0.5)
NERVOUS SYSTEM		
CONVULS	0 (0.0)	1 (0.5)
DEPRESSION	3 (1.6)	1 (0.5)
DEPRESSION PSYCHOTIC	1 (0.5)	0 (0.0)
EMOTION LABIL	0 (0.0)	2 (1.1)
INTRACRAN HYPERTENS	1 (0.5)	0 (0.0)
NEUROPATHY	1 (0.5)	0 (0.0)
PARESTHESIA	0 (0.0)	2 (1.1)
PSYCHOSIS	0 (0.0)	1 (0.5)
THINKING ABNORM	1 (0.5)	0 (0.0)
VERTIGO	1 (0.5)	0 (0.0)

Patients may be reported more than once within a body system, but can occur once at most within a COSTART.
If a patient has more than one adverse event within a COSTART, then the most severe event is summarized.
TESS (Treatment Emergent Signs and Symptoms) is defined as those events with onset date after qualifying visit date and within 42 days after the last known study medication date

Source: s:\genelabs\dhea\g19502\sasfile\programs\t_ae2.sas 6.12 22FEB01
ACRO T-33 AE by Severity

TABLE 27

PATIENTS WITH SEVERE ADVERSE EVENTS BY BODY SYSTEM AND COSTART

	Placebo (N=192)	GI.701 200 mg (N=189)
RESPIRATORY		
CARCINOMA LUNG	1 (0.5)	0 (0.0)
DYSPNEA	0 (0.0)	1 (0.5)
EDEMA LUNG	0 (0.0)	1 (0.5)
NASAL SEPTUM DIS	1 (0.5)	0 (0.0)
PLEURAL DIS	1 (0.5)	1 (0.5)
RESPIRAT DIS	1 (0.5)	0 (0.0)
DERMATOLOGICAL		
ALOPECIA	1 (0.5)	1 (0.5)
HERPES ZOSTER	1 (0.5)	0 (0.0)
MELANOMA SKIN	1 (0.5)	0 (0.0)
RASH	2 (1.0)	4 (2.1)
SPECIAL SENSES		
PAIN EYE	1 (0.5)	0 (0.0)
PHOTOPHOBIA	1 (0.5)	0 (0.0)
UROGENITAL		
CARCINOMA BREAST	1 (0.5)	0 (0.0)
HEMATURIA	0 (0.0)	1 (0.5)
KIDNEY FAIL	0 (0.0)	1 (0.5)
MENORRHAGIA	0 (0.0)	1 (0.5)
UROGENITAL		
NEPHRITIS	0 (0.0)	1 (0.5)
NEPHROSIS	1 (0.5)	0 (0.0)
OVAR DIS	1 (0.5)	0 (0.0)
UTER DIS	1 (0.5)	0 (0.0)

Patients may be reported more than once within a body system, but can occur once at most within a COSTART.
If a patient has more than one adverse event within a COSTART, then the most severe event is summarized.
TESS (Treatment Emergent Signs and Symptoms) is defined as those events with onset date after qualifying visit date and within 42 days after the last known study medication date
Source: s:\genelabs\dhea\gl9502\sasfile\programs\t_ae2 sas 6.12 15OCT99
ACRO T-33 AE by Severity

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: BODY AS A WHOLE

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	32 (69.6)	32 (80.0)	46 (67.6)	26 (68.4)	26 (61.9)	21 (72.4)	44 (67.7)	36 (67.9)
COSTART								
ALLERG REACT	0 (0.0)	1 (2.5)	2 (2.9)	0 (0.0)	1 (2.4)	1 (3.4)	1 (1.5)	3 (5.7)
ANOMALY CONGEN	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
ASTHENIA	11 (23.9)	14 (35.0)	18 (26.5)	8 (21.1)	8 (19.0)	7 (24.1)	17 (26.2)	13 (24.5)
CELLULITIS	0 (0.0)	0 (0.0)	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CHILLS FEVER	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CYST	1 (2.2)	1 (2.5)	2 (2.9)	3 (7.9)	0 (0.0)	0 (0.0)	1 (1.5)	2 (3.8)
EDEMA FACE	0 (0.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EDEMA GENERAL	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
FEVER	5 (10.9)	6 (15.0)	8 (11.8)	9 (23.7)	4 (9.5)	2 (6.9)	12 (18.5)	4 (7.5)
FLU SYND	11 (23.9)	7 (17.5)	15 (22.1)	9 (23.7)	6 (14.3)	8 (27.6)	14 (21.5)	11 (20.8)
HEADACHE	14 (30.4)	11 (27.5)	21 (30.9)	10 (26.3)	9 (21.4)	6 (20.7)	13 (20.0)	14 (26.4)
HERNIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
INFECT	5 (10.9)	2 (5.0)	6 (8.8)	3 (7.9)	2 (4.8)	2 (6.9)	5 (7.7)	2 (3.8)
INFECT FUNG	1 (2.2)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
INJURY ACCID	2 (4.3)	1 (2.5)	0 (0.0)	1 (2.6)	0 (0.0)	3 (10.3)	1 (1.5)	2 (3.8)
LAB TEST ABNORM	1 (2.2)	0 (0.0)	2 (2.9)	1 (2.6)	2 (4.8)	0 (0.0)	2 (3.1)	4 (7.5)
LE SYND	0 (0.0)	2 (5.0)	4 (5.9)	1 (2.6)	1 (2.4)	0 (0.0)	1 (1.5)	2 (3.8)
MALAISE	1 (2.2)	0 (0.0)	0 (0.0)	1 (2.6)	2 (4.8)	0 (0.0)	1 (1.5)	1 (1.9)
NECK RIGID	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEOPL	0 (0.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	1 (1.5)	1 (1.9)
PAIN	3 (6.5)	3 (7.5)	0 (0.0)	2 (5.3)	1 (2.4)	2 (6.9)	2 (3.1)	0 (0.0)
PAIN ABDO	7 (15.2)	6 (15.0)	9 (13.2)	8 (21.1)	6 (14.3)	2 (6.9)	7 (10.8)	12 (22.6)
PAIN BACK	3 (6.5)	2 (5.0)	0 (0.0)	1 (2.6)	3 (7.1)	3 (10.3)	6 (9.2)	3 (5.7)
PAIN CHEST	7 (15.2)	6 (15.0)	4 (5.9)	3 (7.9)	3 (7.1)	2 (6.9)	5 (7.7)	4 (7.5)
PAIN FLANK	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
PAIN NECK	0 (0.0)	1 (2.5)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
PAIN PELVIC	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
REACT AGGRAV	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)

TABLE 28

Source: r:\genelabs\dhea\fda\newreq\fda\12_21_2000\ae_sled.sas 6.12 19JAN01

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: BODY AS A WHOLE

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
COSTART								
SUICIDE ATTEMPT	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: CARDIOVASCULAR

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	10 (21.7)	16 (40.0)	20 (29.4)	15 (39.5)	13 (31.0)	9 (31.0)	16 (24.6)	20 (37.7)
COSTART								
ANOMALY HEART	0 (0.0)	4 (10.0)	3 (4.4)	3 (7.9)	0 (0.0)	1 (3.4)	1 (1.5)	3 (5.7)
ARTERIOSCLEROSIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
CARDIOMEGALY	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARDIOVASC DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	1 (1.5)	0 (0.0)
CEREBROVASC ACCID	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ECG ABNORM	0 (0.0)	1 (2.5)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EFFUS PERICARD	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EMB PULM	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
FIBRILLAT ATR	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEART ARREST	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEM	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPERTENS	0 (0.0)	2 (5.0)	4 (5.9)	0 (0.0)	4 (9.5)	2 (6.9)	2 (3.1)	4 (7.5)
HYPERTENS PULM	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPOTENS	0 (0.0)	0 (0.0)	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
INFARCT MYOCARD	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
MIGRAINE	1 (2.2)	2 (5.0)	3 (4.4)	0 (0.0)	2 (4.8)	0 (0.0)	3 (4.6)	1 (1.9)
MYOCARDITIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PALPITAT	0 (0.0)	1 (2.5)	2 (2.9)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
PERICARDITIS	1 (2.2)	3 (7.5)	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	2 (3.1)	2 (3.8)
SYNCOPE	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	1 (3.4)	0 (0.0)	0 (0.0)
TACHYCARDIA	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TACHYCARDIA SUPVENT	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THROM	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
THROMBOPHLEB DEEP	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VASC DIS	2 (4.3)	0 (0.0)	1 (1.5)	4 (10.5)	3 (7.1)	1 (3.4)	1 (1.5)	1 (1.9)
VASC DIS PERIPH	5 (10.9)	6 (15.0)	7 (10.3)	2 (5.3)	3 (7.1)	4 (13.8)	7 (10.8)	5 (9.4)
VASCULITIS	0 (0.0)	1 (2.5)	3 (4.4)	2 (5.3)	1 (2.4)	0 (0.0)	0 (0.0)	3 (5.7)
VASODILAT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	1 (1.5)	5 (9.4)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: CARDIOVASCULAR

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
COSTART								
VEIN VARICOSE	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: DIGESTION

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	23 (50.0)	16 (40.0)	35 (51.5)	17 (44.7)	14 (33.3)	11 (37.9)	28 (43.1)	25 (47.2)
COSTART								
ABSCESS PERIODONT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
ANOREXIA	3 (6.5)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
APPETITE INC	2 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
CHOLECYST	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
CHOLELITH	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (2.4)	1 (3.4)	0 (0.0)	0 (0.0)
COLITIS	0 (0.0)	0 (0.0)	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CONSTIP	2 (4.3)	1 (2.5)	0 (0.0)	1 (2.6)	1 (2.4)	0 (0.0)	2 (3.1)	2 (3.8)
DIARRHEA	2 (4.3)	2 (5.0)	4 (5.9)	1 (2.6)	2 (4.8)	0 (0.0)	4 (6.2)	6 (11.3)
DRY MOUTH	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
DYSPEPSIA	4 (8.7)	3 (7.5)	5 (7.4)	0 (0.0)	5 (11.9)	4 (13.8)	3 (4.6)	5 (9.4)
DYSPHAGIA	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)
ERUCTAT	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ESOPHAGITIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
FLATUL	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.9)	1 (2.4)	0 (0.0)	1 (1.5)	0 (0.0)
GASTRITIS	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.6)	0 (0.0)
GASTROENTERITIS	1 (2.2)	2 (5.0)	2 (2.9)	1 (2.6)	1 (2.4)	1 (3.4)	2 (3.1)	2 (3.8)
GI DIS	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEM GI	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
HEM RECTAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
HEMATEMESIS	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPER GUM	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LIVER FUNC ABNORM	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MELENA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
MONILIA ORAL	0 (0.0)	0 (0.0)	4 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	1 (1.9)
NAUSEA	3 (6.5)	1 (2.5)	2 (2.9)	4 (10.5)	1 (2.4)	3 (10.3)	3 (4.6)	3 (5.7)
NAUSEA VOMIT	0 (0.0)	0 (0.0)	3 (4.4)	3 (7.9)	1 (2.4)	0 (0.0)	1 (1.5)	1 (1.9)
PANCREATITIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (3.4)	2 (3.1)	0 (0.0)
PAROTID ENLARGE	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: DIGESTION

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
COSTART								
RECTAL DIS	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	0 (0.0)
SALIV GLAND ENLARGE	1 (2.2)	0 (0.0)	1 (1.5)	2 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SIALADENITIS	0 (0.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
STOMATITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
STOMATITIS ULCER	10 (21.7)	9 (22.5)	18 (26.5)	7 (18.4)	4 (9.5)	3 (10.3)	13 (20.0)	8 (15.1)
TONGUE DIS	0 (0.0)	0 (0.0)	1 (1.5)	2 (5.3)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
TOOTH CARIES	1 (2.2)	0 (0.0	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOOTH DIS	1 (2.2)	0 (0.0)	3 (4.4)	1 (2.6)	1 (2.4)	0 (0.0)	0 (0.0)	2 (3.8)
VOMIT	1 (2.2)	0 (0.0)	1 (1.5)	2 (5.3)	0 (0.0)	0 (0.0)	2 (3.1)	4 (7.5)

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: ENDOCRINE

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	2 (4.3)	0 (0.0)	0 (0.0)	1 (2.6)	2 (4.8)	1 (3.4)	2 (3.1)	0 (0.0)
COSTART								
CUSHINGS SYND	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
DIABETES MELL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
GOITER	2 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPOTHYR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
THYR DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
THYROIDITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: HEMATOLOGIC AND LYMPHATIC

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	7 (15.2)	6 (15.0)	14 (20.6)	14 (36.8)	3 (7.1)	6 (20.7)	11 (16.9)	8 (15.1)
COSTART								
ANEMIA	0 (0.0)	2 (5.0)	2 (2.9)	1 (2.6)	0 (0.0)	1 (3.4)	1 (1.5)	1 (1.9)
ANEMIA HYPOCHROM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
ECCHYMOSIS	1 (2.2)	0 (0.0)	3 (4.4)	3 (7.9)	0 (0.0)	1 (3.4)	1 (1.5)	1 (1.9)
ESR INC	1 (2.2)	1 (2.5)	0 (0.0)	3 (7.9)	0 (0.0)	2 (6.9)	2 (3.1)	0 (0.0)
LEUKOPENIA	2 (4.3)	2 (5.0)	3 (4.4)	5 (13.2)	1 (2.4)	1 (3.4)	3 (4.6)	1 ([illegible].9)
LYMPHADENO	3 (6.5)	3 (7.5)	5 (7.4)	5 (13.2)	2 (4.8)	1 (3.4)	4 (6.2)	4 (7.5)
LYMPHOMA LIKE REACT	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PROTHROMBIN DEC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.9)
PURPURA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
SPLENOMEGALY	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THROMBOCYTOPENIA	0 (0.0)	0 (0.0)	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
WBC ABNORM	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: METABOLIC AND NUTRITIONAL

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	16 (34.8)	8 (20.0)	11 (16.2)	9 (23.7)	6 (14.3)	11 (37.9)	16 (24.6)	11 (20.8)
COSTART								
ALBUMINURIA	1 (2.2)	3 (7.5)	3 (4.4)	2 (5.3)	0 (0.0)	4 (13.8)	7 (10.8)	4 (7.5)
ANEMIA B12 DEFIC	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CREATININE CLEAR DEC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
CREATININE INC	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	3 (4.6)	1 (1.9)
DEHYDRAT	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIABETES MELL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	1 (1.9)
EDEMA	3 (6.5)	1 (2.5)	1 (1.5)	2 (5.3)	2 (4.8)	2 (6.9)	3 (4.6)	2 (3.8)
GOUT	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HYPERGLYCEM	1 (2.2)	0 (0.0)	0 (0.0)	1 (2.6)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
HYPOGLYCEM	1 (2.2)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PHOSPHATASE ALK INC	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
WEIGHT DEC	4 (8.7)	2 (5.0)	5 (7.4)	3 (7.9)	2 (4.8)	3 (10.3)	4 (6.2)	3 (5.7)
WEIGHT INC	4 (8.7)	2 (5.0)	4 (5.9)	1 (2.6)	1 (2.4)	2 (6.9)	2 (3.1)	1 (1.9)

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: MUSCULOSKELETAL

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	33 (71.7)	30 (75.0)	41 (60.3)	25 (65.8)	24 (57.1)	14 (48.3)	36 (55.4)	34 (64.2)
COSTART								
ARTHRALGIA	18 (39.1)	20 (50.0)	24 (35.3)	9 (23.7)	16 (38.1)	11 (37.9)	24 (36.9)	17 (32.1)
ARTHRITIS	8 (17.4)	7 (17.5)	17 (25.0)	10 (26.3)	8 (19.0)	3 (10.3)	16 (24.6)	18 (34.0)
BONE DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	1 (1.5)	0 (0.0)
BONE FRACT SPONTAN	2 (4.3)	0 (0.0)	3 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.6)	2 (3.8)
BURSITIS	3 (6.5)	2 (5.0)	1 (1.5)	0 (0.0)	3 (7.1)	1 (3.4)	2 (3.1)	1 (1.9)
CRAMPS LEG	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
FIBRO TENDON	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
JOINT DIS	2 (4.3)	3 (7.5)	4 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	2 (3.8)
MYALGIA	20 (43.5)	17 (42.5)	18 (26.5)	14 (36.8)	11 (26.2)	4 (13.8)	10 (15.4)	17 (32.1)
MYASTHENIA	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MYOSITIS	0 (0.0)	1 (2.5)	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
OSTEOMYELITIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OSTEOPOROSIS	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
PAIN BONE	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	1 (1.9)
TENDON DIS	0 (0.0)	1 (2.5)	0 (0.0)	1 (2.6)	1 (2.4)	0 (0.0)	2 (3.1)	1 (1.9)
TENOSYNOVITIS	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	2 (6.9)	2 (3.1)	0 (0.0)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: NERVOUS SYSTEM

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	25 (54.3)	19 (47.5)	25 (36.8)	12 (31.6)	13 (31.0)	16 (55.2)	23 (35.4)	21 (39.6)
COSTART								
AGITATION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
AMNESIA	3 (6.5)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ANXIETY	4 (8.7)	1 (2.5)	2 (2.9)	0 (0.0)	1 (2.4)	1 (3.4)	3 (4.6)	1 (1.9)
ATAXIA	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
BRAIN SYND ACUTE	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
CEREBROVASC ACCID	1 (2.2)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CHOREOATHETOSIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
CONFUS	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CONVULS	2 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	0 (0.0)
CONVULS GRAND MAL	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DEPRESSION	7 (15.2)	9 (22.5)	11 (16.2)	3 (7.9)	7 (16.7)	6 (20.7)	9 (13.8)	6 (11.3)
DEPRESSION PSYCHOTIC	0 (0.0)	1 (2.5)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DIPLOPIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
DIZZINESS	3 (6.5)	1 (2.5)	1 (1.5)	4 (10.5)	0 (0.0)	4 (13.8)	4 (6.2)	2 (3.8)
DREAM ABNORM	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
EMOTION LABIL	1 (2.2)	0 (0.0)	1 (1.5)	0 (0.0)	1 (2.4)	0 (0.0)	2 (3.1)	0 (0.0)
HYPERESTHESIA	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
HYPERTONIA	0 (0.0)	1 (2.5)	1 (1.5)	1 (2.6)	2 (4.8)	1 (3.4)	0 (0.0)	2 (3.8)
HYPESTHESIA	1 (2.2)	2 (5.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
INSOMNIA	4 (8.7)	4 (10.0)	2 (2.9)	0 (0.0)	4 (9.5)	3 (10.3)	3 (4.6)	6 (11.3)
INTRACRAN HYPERTENS	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ISCHEMIA CEREBR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
LIBIDO DEC	1 (2.2)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LIBIDO INC	1 (2.2)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (3.4)	1 (1.5)	0 (0.0)
MYELITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
NERVOUSNESS	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	1 (3.4)	1 (1.5)	2 (3.8)
NEURALGIA	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEURITIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: NERVOUS SYSTEM

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
COSTART								
NEURITIS PERIPH	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEUROPATHY	2 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	2 (3.1)	0 (0.0)
PARALYSIS FACIAL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
PARESTHESIA	1 (2.2)	3 (7.5)	1 (1.5)	2 (5.3)	1 (2.4)	0 (0.0)	1 (1.5)	2 (3.8)
PERSON DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
PSYCHOSIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
SLEEP DIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SOMNOLENCE	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THINKING ABNORM	2 (4.3)	2 (5.0)	2 (2.9)	1 (2.6)	1 (2.4)	1 (3.4)	5 (7.7)	2 (3.8)
TREMOR	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
TWITCH	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VERTIGO	1 (2.2)	0 (0.0)	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.9)

STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: RESPIRATORY

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	20 (43.5)	15 (37.5)	29 (42.6)	15 (39.5)	7 (16.7)	11 (37.9)	24 (36.9)	13 (24.5)
COSTART								
ASTHMA	0 (0.0)	1 (2.5)	0 (0.0)	1 (2.6)	1 (2.4)	3 (10.3)	0 (0.0)	0 (0.0)
BRONCHITIS	1 (2.2)	2 (5.0)	1 (1.5)	3 (7.9)	0 (0.0)	2 (6.9)	3 (4.6)	2 (3.8)
CARCINOMA LUNG	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
COUGH INC	0 (0.0)	2 (5.0)	2 (2.9)	1 (2.6)	0 (0.0)	0 (0.0)	2 (3.1)	1 (1.9)
DYSPNEA	7 (15.2)	2 (5.0)	4 (5.9)	2 (5.3)	1 (2.4)	1 (3.4)	3 (4.6)	3 (5.7)
EDEMA LUNG	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
EFFUS PLEURAL	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EPISTAXIS	2 (4.3)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.9)
LARYNGITIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
LUNG DIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
NASAL SEPTUM DIS	3 (6.5)	3 (7.5)	3 (4.4)	3 (7.9)	0 (0.0)	0 (0.0)	3 (4.6)	0 (0.0)
PHARYNGITIS	2 (4.3)	3 (7.5)	4 (5.9)	0 (0.0)	0 (0.0)	1 (3.4)	4 (6.2)	1 (1.9)
PLEURAL DIS	4 (8.7)	2 (5.0)	7 (10.3)	4 (10.5)	5 (11.9)	0 (0.0)	5 (7.7)	4 (7.5)
PNEUMONIA	0 (0.0)	0 (0.0)	1 (1.5)	3 (7.9)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.9)
RESPIRAT DIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (3.4)	1 (1.5)	0 (0.0)
RHINITIS	2 (4.3)	0 (0.0)	3 (4.4)	0 (0.0)	1 (2.4)	0 (0.0)	2 (3.1)	2 (3.8)
SINUSITIS	4 (8.7)	7 (17.5)	6 (8.8)	3 (7.9)	1 (2.4)	3 (10.3)	9 (13.8)	4 (7.5)
VOICE ALTERAT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: DERMATOLOGICAL

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	28 (60.9)	25 (62.5)	39 (57.4)	24 (63.2)	30 (71.4)	21 (72.4)	49 (75.4)	35 (66.0)
COSTART								
ACNE	11 (23.9)	6 (15.0)	7 (10.3)	3 (7.9)	13 (31.0)	10 (34.5)	27 (41.5)	13 (24.5)
ALOPECIA	9 (19.6)	10 (25.0)	16 (23.5)	4 (10.5)	5 (11.9)	4 (13.8)	8 (12.3)	11 (20.8)
DERM CONTACT	1 (2.2)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
DERM FUNG	1 (2.2)	0 (0.0)	1 (1.5)	1 (2.6)	[illegible] (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
ECZEMA	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	[illegible] (0.0)	0 (0.0)	1 (1.5)	1 (1.9)
FURUNCULOSIS	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HAIR DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
HERPES SIMPLEX	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
HERPES ZOSTER	1 (2.2)	0 (0.0)	1 (1.5)	3 (7.9)	0 (0.0)	1 (3.4)	2 (3.1)	1 (1.9)
HIRSUTISM	3 (6.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (19.0)	3 (10.3)	14 (21.5)	6 (11.3)
HYPERTROPHY SKIN	2 (4.3)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LEUKODERMA	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MELANOMA SKIN	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NAIL DIS	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEOPL SKIN	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NODULE SKIN	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
NODULE SUBCUTAN	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	1 (1.5)	0 (0.0)
PRURITUS	0 (0.0)	2 (5.0)	0 (0.0)	0 (0.0)	2 (4.8)	2 (6.9)	2 (3.1)	0 (0.0)
PSORIASIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
RASH	11 (23.9)	14 (35.0)	22 (32.4)	15 (39.5)	18 (42.9)	10 (34.5)	27 (41.5)	20 (37.7)
SEBORRHEA	0 (0.0)	1 (2.5)	0 (0.0)	2 (5.3)	2 (4.8)	2 (6.9)	1 (1.5)	0 (0.0)
SKIN DIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
SKIN DISCOLOR	0 (0.0)	2 (5.0)	1 (1.5)	2 (5.3)	0 (0.0)	1 (3.4)	1 (1.5)	0 (0.0)
SKIN DRY	1 (2.2)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
SWEAT	1 (2.2)	0 (0.0)	2 (2.9)	2 (5.3)	3 (7.1)	2 (6.9)	3 (4.6)	1 (1.9)
ULCER SKIN	0 (0.0)	2 (5.0)	4 (5.9)	1 (2.6)	0 (0.0)	1 (3.4)	1 (1.5)	1 (1.9)
URTICARIA	3 (6.5)	0 (0.0)	2 (2.9)	2 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.7)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: SPECIAL SENSES

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	4 (8.7)	5 (12.5)	8 (11.8)	3 (7.9)	6 (14.3)	4 (13.8)	10 (15.4)	3 (5.7)
COSTART								
AMBLYOPIA	1 (2.2)	1 (2.5)	2 (2.9)	0 (0.0)	1 (2.4)	0 (0.0)	2 (3.1)	0 (0.0)
CATARACT	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (10.3)	1 (1.5)	2 (3.8)
CONJUNCTIVITIS	2 (4.3)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
DEAF	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
DRY EYE	1 (2.2)	1 (2.5)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	2 (3.1)	0 (0.0)
EAR DIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.9)
EXOPHTHALMOS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
GLAUCOMA	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEM EYE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	1 (1.5)	0 (0.0)
LACRIMATION DIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MYDRIASIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
OTITIS EXT	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
OTITIS MED	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
PAIN EAR	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PAIN EYE	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
PHOTOPHOBIA	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PTOSIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
TINNITUS	0 (0.0)	2 (5.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	0 (0.0)
ULCER CORNEAL	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VISION ABNORM	0 (0.0)	0 (0.0)	2 (2.9)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: UROGENITAL

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
Body System Total	11 (23.9)	15 (37.5)	17 (25.0)	11 (28.9)	9 (21.4)	14 (48.3)	21 (32.3)	19 (35.8)
COSTART								
ABORTION	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AMENORRHEA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
BREAST ENLARGE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	0 (0.0)
BREAST FIBROCYST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.9)	0 (0.0)	0 (0.0)
CARCINOMA BREAST	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CERVIX DIS	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
CYSTITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	2 (3.8)
DYSMENORRHEA	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.6)	1 (2.4)	1 (3.4)	0 (0.0)	0 (0.0)
DYSURIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)
GLOMERULITIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEM UTER	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HEM VAGINAL	0 (0.0)	1 (2.5)	0 (0.0)	2 (5.3)	0 (0.0)	1 (3.4)	0 (0.0)	1 (1.9)
HEMATURIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.8)	0 (0.0)	1 (1.5)	4 (7.5)
INFECT URIN TRACT	2 (4.3)	6 (15.0)	5 (7.4)	1 (2.6)	2 (4.8)	4 (13.8)	5 (7.7)	6 (11.3)
KIDNEY CALCULUS	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
KIDNEY FAIL	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
LACTATION FEM	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
LEUKORRHEA	1 (2.2)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MENOPAUSE	0 (0.0)	1 (2.5)	1 (1.5)	0 (0.0)	0 (0.0)	1 (3.4)	2 (3.1)	0 (0.0)
MENORRHAGIA	0 (0.0)	1 (2.5)	2 (2.9)	0 (0.0)	0 (0.0)	1 (3.4)	5 (7.7)	1 (1.9)
METRORRHAGIA	3 (6.5)	0 (0.0)	4 (5.9)	1 (2.6)	1 (2.4)	5 (17.2)	3 (4.6)	1 (1.9)
MONILIA VAGINA	1 (2.2)	0 (0.0)	3 (4.4)	2 (5.3)	1 (2.4)	2 (6.9)	2 (3.1)	2 (3.8)
NEOPL BREAST	2 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.9)	1 (1.5)	0 (0.0)
NEPHRITIS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	2 (3.8)
NEPHROSIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OVAR DIS	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PAIN BREAST	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.1)	1 (1.9)
PAP SMEAR SUSP	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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STUDY GL95-02

ADVERSE EVENTS BY BODY SYSTEM, COSTART, BASELINE SLEDAI AND TREATMENT
(ALL RANDOMIZED PATIENTS)

BODY SYSTEM: UROGENITAL

	Placebo				200 mg			
Baseline SLEDAI	0-2 (N= 46)	>2-4 (N= 40)	>4-8 (N= 68)	>8 (N= 38)	0-2 (N= 42)	>2-4 (N= 29)	>4-8 (N= 65)	>8 (N= 53)
COSTART								
PREGN UNINTEND	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.4)	1 (1.5)	0 (0.0)
PYURIA	0 (0.0)	2 (5.0)	1 (1.5)	1 (2.6)	1 (2.4)	1 (3.4)	0 (0.0)	1 (1.9)
URIN ABNORM	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
URIN TRACT DIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)
URIN URGENCY	2 (4.3)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
UTER DIS	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VAGINITIS	0 (0.0)	2 (5.0)	1 (1.5)	1 (2.6)	1 (2.4)	1 (3.4)	3 (4.6)	0 (0.0)

TABLE 29

CHANGES IN SERUM ESTRADIOL AND MENOPAUSAL STATUS

Estradiol (pg/mL)			
Treatment Group		**Baseline**	**Change from Baseline to Last On-Treatment Visit**
Pre-Menopausal	Mean (SD)	97.8 (75.57)	-8.9 (106.60)
Placebo	*Median*	**74.2**	**0.3**
N=63	Range	20.3/373.5	-345.4/259.1
Pre-Menopausal	Mean (SD)	85.6 (73.10)	1.0 (104.13)
GL701	*Median*	**63.9**	**1.5**
N=71	Range	1.4/341.1	-259.4/359.7
Post-Menopausal	Mean (SD)	43.2 (50.03)	5.5 (71.65)
No estrogen therapy[1]	*Median*	**21.3**	**0.0**
Placebo	Range	1.4/179.9	-92.1/331.9
N=33			
Post-Menopausal	Mean (SD)	32.5 (66.78)	5.7 (76.23)
No estrogen therapy	*Median*	**3.1**	**17.2**
GL701	Range	1.4/267.9	-256.7/166.2
N=23			
Post-Menopausal	Mean (SD)	114.9 (142.13)	-21.4 (134.70)
Estrogen therapy[2]	*Median*	**68.2**	**0.4**
Placebo	Range	1.4/643.8	-430.2/152.2
N=30			
Post-Menopausal	Mean (SD)	87.5 (74.32)	33.6 (79.43)
Estrogen Therapy	*Median*	**82.3**	**32.1**
GL701	Range	14.0/390.8	-106.5/263.6
N=29			

1. Not receiving estrogen therapy at any time during the study.
2. Receiving estrogen therapy at baseline and at end of study drug treatment. Five patients receiving estrogen therapy at baseline, but not at end of study are excluded from this analysis.

Source: Table 63, Table 70, Table 71

TABLE 30

CHANGE FROM BASELINE FOR TESTERONE AND SHBG

Testosterone (ng/dl)[1]			
Treatment Group		**Baseline**	**Change from Baseline to Last On-Treatment Visit**
Placebo N=131	Mean (SD) ***Median*** Range P value	20.4 (19.96) 16.0 4.0/163.0	-1.7 (14.30) **0.0** -44.0/48.0 0.1793
GL701 200 mg/day N=123	Mean (SD) ***Median*** Range P value	21.3 (18.64) 16.0 4.0/102.0	44.3 (50.40) **38.00** -28.0/398.0 0.0000
SHBG (nmol/L)[2]			
Placebo N=124	Mean (SD) ***Median*** Range P value	71.2 (62.09) 53.0 10.0/365.0	0.5 (29.29) **-2.0** -103.01/34.0 0.8352
GL701 200 mg/day N=112	Mean (SD) ***Median*** Range P value	62.9 (34.58) 60.5 6.0/199.0	-30.7(25.77) **-25.0** -114.0/20.0 0.0000

1. P = 0. 001 for between treatment comparison
2. P = 0.001 for between treatment comparison

Source: Tables 56 and 58

BETWEEN- AND WITHIN-TREATMENT ANALYSES FOR THE CHANGE FROM BASELINE* TO LAST VISIT**
FOR SELECTED LABORATORY TESTS

	Placebo				GL701 200 mg				Between P-value
	N	Mean	SD	Within P-value	N	Mean	SD	Within P-value	
TRIGLYCERIDES (mg/dL)	178	12.48	65.47	0.0119	171	-18.37	71.22	0.0009	0.0001
CHOLESTEROL (mg/dL)	178	1.61	29.48	0.4666	171	-10.34	30.81	<0.0001	0.0002
HDL CHOLESTEROL (mg/dL)	178	-0.57	11.34	0.5011	171	-6.85	11.26	<0.0001	0.0001
LDL CHOLESTEROL (mg/dL)	177	0.04	24.20	0.9827	169	-1.19	26.57	0.5614	0.6529
LDL/HDL RATIO	177	0.07	0.67	0.1911	169	0.35	0.85	<0.0001	0.0005
CHOLESTEROL/HDL RATIO	178	0.13	0.83	0.0345	171	0.36	0.97	<0.0001	0.0188
TESTOSTERONE (ng/dL)	131	-1.69	14.30	0.1793	123	44.31	50.40	<0.0001	0.0001
ESTRADIOL (pg/mL)	131	-7.74	104.41	0.3978	124	11.88	97.48	0.1771	0.1226
SEX HORMONE BIND GLOB (nmol/L)	124	0.55	29.29	0.8352	112	-30.65	25.77	<0.0001	0.0001
ANTI-DOUBLE STRANDED DNA (IU/ML)	178	5.84	145.64	0.5931	169	20.02	130.04	0.0470	0.3404
COMPLEMENT C3 (MG/DL)	178	-2.48	17.80	0.0644	169	-7.20	18.03	<0.0001	0.0147
COMPLEMENT C4 (MG/DL)	178	-0.70	3.63	0.0106	169	-0.91	3.28	0.0004	0.5852

* Baseline refers to the last pre-dosing measurement taken. Note: Laboratory measurements were scheduled to be taken at the screening visit.
** Last visit refers to the last postbaseline measurement of an on-treatment visit.
Within p-value is from the paired t-test.
Between p-value is from an ANOVA model with treatment as a factor.

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ACRO T-55 Laboratory Test P-values

TABLE 31

TABLE 32

SUMMARY OF MOST FREQUENT ADVERSE EVENTS REPORTED DURING THE STUDY IN ≥ 5% OF PATIENTS

COSTART Term	Number (%)
Acne	69 (22.0)
Rash	65 (20.7)
Asthenia	63 (20.1)
Pain	63 (20.1)
Infection	59 (18.8)
Arthralgia	58 (18.5)
Headache	52 (16.6)
Urinary Tract Infection	35 (11.1)
Arthritis	34 (10.8)
Alopecia	31 (9.9)
Myalgia	28 (8.9)
Depression	27 (8.6)
Abdominal Pain	23 (7.3)
Sinusitis	23 (7.3)
Joint disease	22 (7.0)
Pain back	21 (6.7)
Hirsutism	20 (6.4)
Chest Pain	19 (6.1)
Nausea	19 (6.1)
Insomnia	18 (5.7)
Bronchitis	18 (5.7)
Stomatitis ulcer	17 (5.4)
Metrorrhagia	17 (5.4)
Peripheral Edema	16 (5.1)

Source: Table 15

TABLE 33

SEVERE ADVERSE EVENTS IN ≥ 0.5% OF PATIENTS BY COSTART AND SEVERITY
(ALL RANDOMIZED PATIENTS)

	GL701 (N=314)		
Description	Mild	Moderate	Severe
ASTHENIA	25 (8.0)	30 (9.6)	8 (2.5)
HEADACHE	33 (10.5)	12 (3.8)	7 (2.2)
ARTHRALGIA	33 (10.5)	21 (6.7)	4 (1.3)
PAIN	41 (13.1)	18 (5.7)	4 (1.3)
DYSPNEA	4 (1.3)	1 (0.3)	4 (1.3)
ARTHRITIS	17 (5.4)	14 (4.5)	3 (1.0)
DEPRESSION	10 (3.2)	14 (4.5)	3 (1.0)
LE SYNDROME	5 (1.6)	7 (2.2)	3 (1.0)
MIGRAINE	4 (1.3)	4 (1.3)	3 (1.0)
PNEUMONIA	1 (0.3)	4 (1.3)	3 (1.0)
INFECTION	36 (11.5)	21 (6.7)	2 (0.6)
RASH	43 (13.7)	20 (6.4)	2 (0.6)
MYALGIA	16 (5.1)	10 (3.2)	2 (0.6)
URINARY TRACT INFECTION	23 (7.3)	10 (3.2)	2 (0.6)
CHEST PAIN	11 (3.5)	6 (1.9)	2 (0.6)
CONVULSIONS	3 (1.0)	2 (0.6)	2 (0.6)
WEIGHT DECREASE	6 (1.9)	1 (0.3)	2 (0.6)
ALBUMINURIA	2 (0.6)	0 (0.0)	2 (0.6)
RESPIRAT DISEASE	1 (0.3)	0 (0.0)	2 (0.6)
KIDNEY FUNCTION ABNORMALITY	0 (0.0)	0 (0.0)	2 (0.6)

Source: Table 16

TABLE 34

ADVERSE EVENTS BY RACE WITH A ≥ 5% FREQUENCY

Costart Term	Caucasian	GL701 African American	Other
	(N=221)	(N= 67)	(N= 26)
Body System:			
Dermatological	133 (60.2)	24 (35.8)	18 (69.2)
Metabolic and nutritional	41 (18.6)	9 (13.4)	5 (19.2)
Hematologic and Lymphatic	28 (12.7)	4 (6.0)	7 (26.9)
Individual Adverse Events:			
ACNE	50 (22.6)	9 (13.4)	10 (38.5)
RASH	49 (22.2)	10 (14.9)	6 (23.1)
PAIN	47 (21.3)	10 (14.9)	6 (23.1)
ARTHRALGIA	45 (20.4)	7 (10.4)	6 (23.1)
HEADACHE	31 (14.0)	15 (22.4)	6 (23.1)
ALOPECIA	23 (10.4)	3 (4.5)	5 (19.2)
SINUSITIS	20 (9.0)	2 (3.0)	1 (3.8)
HIRSUTISM	16 (7.2)	1 (1.5)	3 (11.5)
INSOMNIA	15 (6.8)	1 (1.5)	2 (7.7)
JOINT DISEASE	13 (5.9)	7 (10.4)	2 (7.7)
PERIPHERAL VASCULAR DISEASE	12 (5.4)	0 (0.0)	0 (0.0)
ABDOMINAL PAIN	10 (4.5)	8 (11.9)	5 (19.2)

Source: Table 21

TABLE 35

REASONS FOR GL701 DOSE REDUCTION

Patient Number	GL701 or Placebo Dose in Double-Blind Phase	Duration (days) of Treatment with GL701 in GL95-01 before Dose Reduction	Reasons for Dose Reduction
16006	GL95-02 placebo	100	Acne
18032	GL95-02 placebo	183	Acne
18041	GL95-02 placebo	205	Acne
18045	GL95-02 placebo	64	Acne
19001	GL94-01 placebo	62	Acne
22001	GL94-01 100 mg	195	Acne
25002	GL94-01 100 mg	93	Acne
33002	GL95-02 200 mg	82	Acne
36002	GL95-02 200 mg	18	Acne
36005	GL95-02 200 mg	192	Acne
38007	GL95-02 placebo	225	Acne
38010	GL95-02 200 mg	85	Acne
38014	GL95-02 placebo	16	Acne
36010	GL95-02 placebo	171	Acne on chest
12007	GL94-01 placebo	63	Acne on face, chest, axilla
38006	GL95-02 placebo	204	Acne vulgaris, malar rash intermittent
19002	GL94-01 placebo	62	Acne, decreased libido
38030	GL95-02 placebo	219	Acne, weight gain
23011	GL95-02 200 mg	215	Cyclical breast tenderness
43009	GL95-02 200 mg	61	Emotional lability
27002	GL94-01 100 mg	34	Emotional lability
36006	GL95-02 placebo	92	Erythema rash on chest, alopecia
36004	GL95-02 placebo	198	Facial hair growth
40002	GL95-02 placebo	150	Hair growth

REASONS FOR GL701 DOSE REDUCTION *CONTINUED*

Patient Number	GL701 or Placebo Dose in Double-Blind Phase	Duration (days) of Treatment with GL701 in GL95-01 before Dose Reduction	Reasons for Dose Reduction
13003	GL94-01 100 mg	95	Hirsutism
38021	GL95-02 placebo	216	Increase facial, chest, back acne, weight gain
14015	GL95-02 200 mg	84	Increased facial hair, heavier menstrual cycle
20005	GL94-01 200 mg	83	Intermittent headaches
19005	GL94-01 100 mg	57	Menstrual cycle every 2 weeks
18023	GL94-01 placebo	270	Reason unknown
18034	GL95-02 placebo	217	Reason unknown
41001	GL95-02 200 mg	59	Reason unknown
16003	GL94-01 100 mg	191	Scalp irritation with excessive oiliness
27007	GL94-01 placebo	228	Unknown

Source: Listing L-17, Appendix 14.2

REASONS FOR GL701 DOSE INCREASE

Patient Number	Adverse Event
15021	Arthritis flare, myalgia (proximal muscle & neck), marked increase in fatigue after discontinuing GL701 200 mg/day
22001	Increased fatigue, decreased cognitive functioning after reducing GL701 from 200 to 150 mg/day
38007	Decreased cognitive functioning, fatigue, increased joint pains after reducing GL701 from 200 to 100 mg/day

Source: Listing L-17, Appendix 14.2

TABLE 36

DEATHS DURING STUDY GL95-01 OR IN THE FOLLOW-UP PERIOD

Patient ID	Reason for Death	Comment	Previous Study	Treatment in Previous Study
12005	Cardiac Arrest-death	Event occurred 1 month following completion of GL95-01	GL94-01	Placebo
25003	Death related to SLE	Event occurred at Month 5.75 of GL95-01	GL94-01	GL701 200 mg
25005	Death due to cerebrovascular accident	Coexisting conditions – hypertension and diabetes mellitus	GL94-01	GL701 200 mg
27001	Death due to cardiorespiratory insufficiency related to SLE and emphysema	Event occurred in follow-up period at 6 weeks post discontinuation of GL701	GL94-01	GL701 200 mg

Source: Table 22

Patient 12005 (placebo from GL94-01 / 372 days in GL95-01): This 46-year-old Caucasian patient had a long of history of thrombotic events preceding her participation in Study GL94-01 related to anticardiolipin syndrome. She expired from a cardiac arrest one month following discontinuation of study drug.

Patient 25003 (200 mg GL701 from GL94-01 / 162 days in GL95-01): This 43 year old Hispanic patient died from complications related to her systemic lupus erythematosus after approximately 5.75 months of participation in Study GL95-01. The patient had had preexisting aortic stenosis, and during the study, she underwent cardiac catheterization for evaluation of progressive cardiac dysfunction. This patient eventually suffered cardiac arrest and could not be resuscitated. Autopsy findings included fibrinous endocarditis of the aortic valve, a remote myocardial infarct, thought to be probably embolic, and lupus-related glomerulonephritis, all believed due to SLE.

Patient 25005 (200 mg GL701 from GL94-01 / 335 days in GL95-01): This 50 year old African-American patient died from complications related to a cerebrovascular accident at month 11 of her participation in Study GL95-01. She had previously received 200 mg GL701 as part of Study GL94-01. The patient had a history of hypertension and diabetes mellitus. She was treated with a number of medications prior to entry into Study GL95-01.

Blood pressure on admission to Study GL94-01 was 146/88; on admission to Study GL95-01 it was 146/110. The investigator indicated that he believed this event was related to the patient's longstanding history of hypertension and diabetes.

Patient 27001 (200 mg GL701 from GL94-01 / 260 days in GL95-01): This 67 year old patient developed 3rd degree heart block with cardiorespiratory insufficiency at Month 6 of GL95-01. She had previously completed Study GL94-01 during which she received GL701 200 mg/day. The patient had a history of chronic respiratory insufficiency related to emphysema as well as neuromuscular weakness with diaphragmatic involvement (shrinking lung syndrome) related to her lupus. She died of respiratory insufficiency 6 weeks after discontinuation of study drug.

10.3.2 Serious Adverse Events Resulting in Expedited Reports

Four patients experienced serious adverse events resulting in expedited reports. Narratives for these patients are presented below. A complete listing, along with narratives, of all serious adverse events that occurred during the study to date is provided in **Appendix 14.1.13.**

Patient 12005: As described above, This 46-year-old Caucasian patient had a long of history of thrombotic events preceding her participation in Study GL94-01 related to anticardiolipin syndrome. She expired from a cardiac arrest one month following discontinuation of study drug. No autopsy was performed.

Patient 20003: Transverse myelitis occurred in this 23 year old patient 31 days following completion of Study GL95-01. She had previously completed Study GL94-01 as Patient 20221 (GL701 200 mg/d). The patient's most recent flare of cerebritis was in 1994, prior to entering Study GL94-01 and this recurred at Month 3 of Study GL94-01 while she was receiving 10 mg/day of prednisone.

Three days prior to scheduled completion of Study GL95-01, the patient noted onset of nonproductive cough. Physical examination was unremarkable and chest x-ray was without evidence of pneumonia. The incident was considered possibly related to an early lupus flare and the patient's prednisone dose was increased from 5 to 10 mg/day. As the patient continued to feel well over the following weeks, she self-reduced her prednisone dose to 5 mg/d. Approximately 6 weeks following completion of her participation in the open-label Study GL95-01, the patient presented with transverse myelitis. She was treated with high dose cyclcophosphamide with gradual resolution of her motor weakness.

The relationship of this serious adverse event to the patient's completing Study GL95-01 or tapering her prednisone to 5 mg/day is unknown

Patient 20006: A 32-year-old woman participating in Study GL95-01 was hospitalized following approximately 4 months of participation in the study for deep vein thrombosis and pulmonary embolism. The patient previously had received placebo as Patient 20433 in Study GL95-02. The investigator indicated the event was most likely due to the patient's SLE, particularly in the setting of anticardiolipin antibodies, but the investigator could not rule out a potential relationship between GL701 and lupus coagulapathy and consequently assessed the event as "possibly related" to treatment with GL701.

Patient 48004: A 28 year old woman participating in the open-label GL95-01 study was hospitalized with an acute cerebrovascular ischemic event characterized by partial right hemiparesis without sensory loss, right facial droop, and slurred speech. She had received placebo for 12 months in Study GL95-02 and was treated with GL701 200 mg/day for approximately 8 months as part of the open label GL95-02 study.

The patient had a complicated medical history including predisposing factors such as anatomical abnormalities of the CNS, a CNS shunt, use of oral contraceptives, and was receiving numerous other drugs which might have influenced this event. This event is also consistent with manifestations of neuropsychiatric lupus.

APPENDIX 14.1.13

LISTING OF PATIENTS WHO EXPERIENCED SERIOUS ADVERSE EVENTS

Patient # **03002** (150 days)
This 47 year-old Caucasian female with a history of depression was hospitalized on 12/05/95 with complaints of severe joint and muscle pains. She reported that she had been bedridden for at least four weeks. Physical exam, chest x-ray, and lab evaluations were performed. She was diagnosed as suffering from severe depression and started on Paxil. Elavil was added to improve her sleep and Ultram for pain control. Her prednisone was increased from 3.5 to 5 and because her TSH levels were elevated she was started on 0.05 of Synthroid prior to being discharged, 4 days later, December 9, 1995.

Patient # **12004** (186 days)
This 37 year-old Caucasian female was hospitalized on 01/10/96 for elective bilateral breast reduction and discharged 1/11/96 without complications.

Patient # **12005** (280 days)
This 46 year old Caucasian female has a history of vascular right femoral posterior tibial artery bypass, aorto-bi-femoral bypass grafting for an aortic abdominal aneurysm, right femoral bypass with superficial femoral artery to posterior tibial artery autologous reverse vein bypass and thrombectomy of femoral tibial bypass graft and creation of distal tibial to anterior tibial bypass with autologous vein.

On 3/3/96 she was hospitalized with complaints of ischemic discoloration of the right lower extremity with acute onset of pain and was diagnosed with ischemic right lower extremity. She underwent an Aorta-Femoral Bypass that was unsuccessful and on 3/5/96 the procedure was repeated.

On 7/18/96 this patient died of cardiac arrest.

Patient # **13005** (371 days)
This 42 year-old Caucasian female was diagnosed on 9/5/96 with a benign fibroid and on 10/24/96 was hospitalized and underwent a hysterectomy.

Patient # **14001** (366 days)
This 68 year-old Caucasian female with a history of mitral valve prolapse was hospitalized on 4/15/96 for observation following complaints of increasing chest pain over a 2-day period. After undergoing an EKG and one set of cardiac enzymes (both normal) she was treated with Indocin and Cytotec. She was discharged 7 days later, 4/22/96 and experienced a MI that evening. She was re-admitted to the hospital and diagnosed with acute injury in the inferior leads and underwent a cardiac catheterizatioin and an angioplasty with no complications. She was discharged 6 days later, 4/28/96 on her usual medications and the addition of Nitrostat, Lopressor, Coumadin and aspirin.

Patient # **14002** (271 days)
This 68 year-old Caucasian female was hospitalized on 1/26/96 with pneumonia-like symptoms. After undergoing a lung biopsy she was diagnosed with interstitial lung disease secondary to her chronic use of Macrodantin for urinary tract infections. The Macrodantin was discontinued and she was treated with a 10-day course of oral antibiotics. She was discharged 12 days later on 2/8/96.

Patient # **14003** (57 days post study medication)
This 30 year-old Hispanic female was hospitalized on 6/25/96 for elective bilateral forefoot resection with arthroplasties of the hammer digits. She was discharged one day later, 6/26/96.

Patient # **14012** (225 days)
This 49 year-old Caucasian female was hospitalized on 5/10/96 following a couple of weeks experiencing palpitations, dizziness, soreness in her arms, heaviness in her neck, shoulder pain, and pain in her neck and chest. After undergoing a physical exam and a thallium treadmill test she was diagnosed as experiencing a flare following a recent reduction of her prednisone. She was prescribed a prednisone taper and discharged the next day, 5/11/96.

Patient # **15001** (219 days)
This 58 year-old Caucasian female was hospitalized on 12/14/95 and diagnosed with urosepsis. She was treated with antibiotics and a temporary increase in glucocorticoid. She recovered and was discharged.

Patient # **15007** (43 days)
This 34 year-old African-American female was hospitalized on 7/29/95 with complaints of a seizure. She was treated with Dilantin and discharged 2 days later, 7/31/95.

Patient # **15015** (# of days still pending)
This 47 year-old Caucasian female was hospitalized on 5/21/98 with complaints of chest pain. She underwent a cardiac work-up and a cardiac catheterization was performed. She was discharged 3 days later, 5/24/98.

On October of 1998 this patient was hospitalized again and was diagnosed as having pulmonary hypertension (was noted to be obese, 350 pounds) and infectious complications from the intravenous catheter. She died December 19, 1998.

Patient # **15019** (150 days)
This 35 year-old Caucasian female was hospitalized on 1/16/98 with complaints of runny nose, nausea, vomiting, shortness of breath, dry cough, right pleuritic chest pain, fever and chills. After undergoing a chest X-ray she was diagnosed with chlamydia pneumonia. She was treated with antibiotics and stress steroids and discharged 7 days later, 1/23/98.

Patient # **15021** (230 days)
This 31 year-old Hispanic female with a history of deep vein thrombosis, antiphospholipid antibodies, arthritis, depression, annorexia and pregnancy loss was admitted to the

hospitalized on 6/24/98 with complaints of leg swelling. The attending physician admitted her for the placement of an umbrella catheter. However, the patient's treating physician advised against this procedure, she was treated with Coumadin and released.

On April 25, 1998 this patient was hospitalized and diagnosed with pancytopenia, major depression, arthritis, membranous nephritis and anemia. She was treated with IV steroids and antibiotics and discharged 2 weeks later.

Patient # **18001** (265 days)
This 48 year-old African-American female was hospitalized on 11/29/95 and 2/27/96 for elective carpal tunnel release as an outpatient. She was discharged the same day.

Patient # **18002** (268 days)
This 34 year-old Caucasian female was hospitalized on 12/1/95 with viral gastroenteritis and dehydration. After undergoing IV rehydration she was discharged 3 days later, 12/4/95.

Patient # **18003** (135 days)
This 33 year-old African-American female with a history of angioedema; bacteremia and sepsis possibly related to Pneumococcus or Staphylococcus aureus, was hospitalized on 7/22/95 with shaking and chills and found to be febrile. She was treated with broad-spectrum antibiotics however, her first blood cultures grew Staphylococcus, but subsequent cultures did not. Therefore, antibiotics were stopped; she was afebrile at time of discharge, 5 days later, 7/27/95.

On 10/23/95, this patient was hospitalized for fever and angioedema. She was treated with intravenous antibiotics, which were stopped when all cultures were negative. Her angioedema was treated with an increase in her prednisone from 20 to 30 mg a day. She was discharged 3 days later, 10/26/95.

Patient #**18005** (141 days)
This 22 year-old Asian female was hospitalized on 8/4/95 with complaints of diarrhea, vomiting and headache. After undergoing a chest X-ray, lumbar puncture and fecal cultures she was diagnosed with viral diarrhea. She was initially treated with cefotaxime, ampicillin, ciprofloxacin and stress doses of Solu-Medrol. After 24 hours she was put on a maintenance dose of prednisone 15 mg a day and discharged 2 days later, 8/6/95.

Patient # **18006** (69 days)
This 25 year-old African American female with a history of serositis and polyarthritis was seen in clinic on 12/21/95 following a viral syndrome for approximately one week. She appeared to be weak, listless, and had no appetite. Lab evaluations were performed and because of a panic value with calcium of 15.8 she was contacted and instructed to report to the hospital for admittance. On 12/22/95 the patient was hospitalized and after undergoing laboratory evaluations, chest x-ray, chest CT and a bronchoscopy she was diagnosed with renal failure, hypercalcemia and thrombocytopenia and treated aggressively with hydration and calcitonin. In addition, she was treated with intravenous Solu-Medrol 1000 mg day for

three days. She was discharged on prednisone 60 mg day, Zantax 150 mg b.i.d. and plaquenil 400 mg q.d., 9 days later, 1/6/96 in fair condition.

Patient # **18007** (55 days)
This 53 year-old African American female with a history of Wallenberg's lateral medullary syndrome, hypertension, diabetes mellitus, hypercholesterolemia, gastroesophageal reflux, hypocomplementemia associated with lupus and coronary artery disease was hospitalized March 1994 to undergo a cardiac catheterization. The catheterization showed a 50% narrowing of the LAD, a 70% narrowing of the first marginal branch of the circumflex, a 70% narrowing of the third marginal branch of the circumflex, and total occlusion of the right coronary artery. She declined surgery at that time.

On 5/15/95 she was admitted with increased symptoms including angina at rest and with exertion and underwent a cardiac catheterization followed by a Coronary Artery Bypass Grafting X 4 on 5/17/95. Her hospital course was complicated by a sternal and right thigh wound infection and she was treated with antibiotics and dressing changes. The antibiotics were later discontinued due to early renal dysfunction. The patient was discharged 37 days later, 06/23/95 with instructions to use saline wet-to-dry dressings at home twice a day.

Patient # **18010** (210 days)
This 32 year-old Caucasian female with a history of deep-vein thrombosis was hospitalized on 11/10/95 with complaints of pain when walking, with tenderness in the calf and thigh area. The pain was described as severe and the patient had difficulty ambulating. It was reported that the patient had not been taking Coumadin as instructed and had been skipping medication intermittently. After undergoing a Doppler study, physical examination, chest x-ray, EKG, urine culture and ultrasound of her left leg she was diagnosed with popliteal thrombosis and deep-vein thrombosis of the left leg. She was treated with I.V. heparin, Coumadin, elevation of her leg and warm soaks. She improved and was discharged 5 days later, 11/15/95.

Patient # **18011** (5 days)
This 32 year-old African-American female with a history of hypertension was diagnosed as an outpatient with hip avascular necrosis and core decompression on2/95. This patient was lost to follow-up and no further information is available.

Patient # **18014** (172 days)
This 74 year-old Caucasian female with a long history of hypertension, severe aortic regurgitation with aortic valve replacement and coronary artery bypass graft was hospitalized on 10/26/95 with complaints of epigastric and left axillary pain. Acute myocardial injury was ruled out and daily aspirin therapy was initiated. She was discharged from the hospital 2 days later, 10/28/95 and scheduled to return for stress testing.

On 10/30/95 She returned for cardiac stress testing. After undergoing a physical examination and EKG's she was found to be positive for ischemia

On 12/4/95 she was hospitalized with complaints of disabling angina. After undergoing laboratory evaluations, a cardiac stress test, EKG, nuclear myocardial purfusion imaging, cardiac catheterization and an exercise thallium test with 24-hour reinjection she was diagnosed with ishemia. She was treated with amlodipine 10 mg and a Nitro-Patch 0.4 mg and remained symptom-free the remainder of her hospital stay. She was discharged 2 days later, 12/6/95 in stable condition and scheduled for a follow-up evaluation.

Patient # **18017** (273 days)
This 25 year-old Caucasian female was hospitalized on 4/29/96 with complaints of headache, fever and nonproductive cough. After undergoing a chest x-ray she was diagnosed with community-acquired pneumonia and antibiotics were initiated. On the 4th day she developed worsening of her respiratory status and a subsequent x-ray and CT confirmed increasing infiltrate. Her antibiotic coverage was broadened to include atypical bronchoscopy with brushings. She was diagnosed with legionella pneumonia and treated with high dose erythromycin for a full course of 7 days, recovered and was discharged on 5/12/96, 13 days later.

Patient # **18019** (176 days)
This 41 year-old Caucasian female with a long history of Sjorgren's syndrome was diagnosed with steroid-induced cataracts. She was hospitalized 6/17/96 and underwent cataract surgery consisting of Phacoemulsification with posterior chamber lens implantation of the right eye. The patient tolerated the procedure well and was discharged the same day.

On 6/28/96 this patient was hospitalized with complaints of abdominal pain. After undergoing laboratory assessments she was diagnosed with "abdominal pain (most likely diverticulitis)" and treated with IV antibiotics and discharged 3 days later, 7/1/96.

On 8/5/96 this patient was hospitalized and underwent the same cataract procedure on the left eye as previously performed on her right eye. There were no complications and she was discharged the same day.

Patient # **18022** (269 days)
This 41 year-old African-American female with a history of bilateral knee pain for several years was hospitalized 12/19/95 for pretibial cellulitis.

On 7/26/96 this patient was hospitalized with complaints of bilateral knee pain and after undergoing an MRI, x-rays, and physical examination she was diagnosed with Avascular Necrosis and underwent bilateral distal femoral cord decompressions of both knees.

Patient # **18023** (269 days)
This 42 year-old Caucasian female was hospitalized on 8/24/96 after experiencing a brief clonic seizure. She underwent a MRI of the brain, electroencephalogram, laboratory assessments and physical examination. Although the cause of the seizure was not identified, the investigator assessed that the event is related to either Ritalin or Effexor (specifically their effect on her weight of seventy pounds) rather than her SLE.

Patient # **18030** (267 days)
This 34 year-old Caucasian female was hospitalized on 11/02/96 with complaints of 3-4 days of abdominal pain, nausea and vomiting. After undergoing physical examination, laboratory assessments and ultrasound she was diagnosed with cholelithiasis with obstructive jaundice, and acute pancreatitis. Antibiotics and supplemental steroids were initiated. She underwent a cholecystectomy on 11/05/96 and tolerated the procedure well.

Patient # **18036** (89 days)
This 39 year-old African-American female with a history off osteonecrosis secondary to lupus and steroid use was hospitalized 5/7/98 to undergo arthroscopy and core decompression on both knees. There were no complications and the patient was discharged the next day on 5/8/98 and scheduled to undergo physical therapy.

Patient **#18037** (155 days)
This 31 year old Caucasian female was diagnosed with in situ squamous cell carcinoma of the cervix. Biopsy also showed evidence of infection with human papilloma virus.

Patient # **18043** (107 days)
This 35 year-old African-American female was hospitalized on 6/17/99 with complaints of fever, and had red swollen areas distal to her left elbow and over her left knee. The red swollen areas were aspirated and she underwent chest x-ray, blood and urine cultures. The patient reported that she frequently scratched her skin in these areas. She was diagnosed with cellulitis and treated with an antibiotic. The patient improved and was discharged 2 days later, 6/19/99.

Patient # **19008** (73 days)
This 71 year-old Caucasian female with a history of hypertension and Raynaud's disease was hospitalized on 4/14/96 with complaints of increasing dyspnea, right pleuritic chest pain, and mild nausea. She was taking Cipro as prescribed the day before at a walk-in clinic. After undergoing physical exam, laboratory assessments, chest x-ray and an EKG, she was diagnosed with respiratory distress without hypoxemia and large right pleural effusion. A chest tube was inserted for drainage and she eventually required surgery to clear her lung. The patient was discharged 17 days later on 5/1/96 to a rehabilitation center and subsequently to home 5/21/96.

Patient # **20005** (Approximately 215 Days)
This 35 year-old African-American female was hospitalized and treated for cellulitis and leg ulcer due to trauma. Culture results were positive for E coli and pseudomonas.

Patient # **20006** (# 125 Days)
This 32 year-old African-American female with a history of positive anticardiolipin, Class IV nephritis, pleuropericarditis, and uterine myoma was hospitalized on 9/9/97 following several days of increasing pain in her left leg and substernal chest pain. After undergoing an examination and laboratory test she was started on heparin and coumadin. Additionally, she was examined by vascular surgery and after undergoing a Doppler study she was diagnosed with deep vein thrombosis which had progressed to pulmonary embolism.

On day 2 of her hospitalization the patient developed severe pleuritic chest pain and tachycardia. She was diagnosed with pericardial effusion, consistent with lupus flare and was treated with 80 mg q8 hours of Solu-Medrol.

On September 26, 1997 this patient was hospitalized with complaints of weakness and was diagnosed with severe anemia with an Hct of 15. She was scheduled to undergo transfusion, coumadin was discontinued and she was started on subcutaneous heparin. The gynecologist believes the patient may have had an anovulatory cycle. She had been seen in clinic on September 22, at which time her INR was 4.4. Light menstrual spotting had started and the patient was requested to reduce her coumadin to 2.5/5 mg qod. Over the next several days the bleeding had become more profuse and the patient was instructed to reduce her coumadin to 2.5 mg/d.

On November 15, 1997 this patient was hospitalized with complaints of shortness of breath with intermittent left-sided chest pain and fever to 110.4. After undergoing a chest x-ray the patient was started on antibiotics and commenced full anticoagulation following a ventilation/perfusion scan which was consistent with a probable pulmonary infarction.

Patient # **20009** (70 days)
This 48 year-old Caucasian female was hospitalized on 8/27/97 with complaints of gastroenteritis secondary to viral infection. She was treated with Tagamet and IV fluids for dehydration, dizziness and vomiting. The patient recovered and was discharged 5 days later, 9/2/97.

Patient # **20015** (330 days)
This 54 year-old African-American female was hospitalized on 9/30/98 and treated for pneumonia. She was discharged 5 days later 10/5/98.

Patient # **20016** (Approximately 157 days)
This 22 year-old African-American female was hospitalized 4/98 for depression and recovered from this event 6/98.

Patient # **20018** (241 days)
This 59 year-old African-American female with a history of hypertension and migraine headaches was hospitalized on 12/14/98 with complaints of shortness of breath and an episode of chest pain. She was diagnosed with Congestive Heart Failure

Patient # **20019** (378 days)
This 32 year-old African-American female with a history of persistent proteinuria, nephritis and hypertension was hospitalized on 4/13/98 for control of her blood pressure, shortness of breath and proteinuria with weight loss. After undergoing a renal biopsy, chest x-ray and echocardiogram she was diagnosed with nephritis, and hypertension. She was treated with clonidine 0.2 mg, diazide 37.5, captopril 50 mg, prednisone 10 mg and Imuran 150 mg. She was discharged 4 days later, 4/17/98.

Patient # **20021** (382 days)
This 43 year-old Hispanic female with a history of pleuritis, nephritis and arthritis was hospitalized on 5/4/99 with shortness of breath with pleuritic chest pain, uncontrolled hypertension, proteinuria, joint pain and swelling in both ankles. After undergoing a chest X-ray and a renal biopsy she was diagnosed as having a SLE flare with serositis and nephritis. She was treated with 30 mg of prednisone and was discharged 3 days later, 5/7/99 on 60 mg of prednisone, Immuran, plaquenil 20 mg and Cozaar 50 mg.

Patient # **23001** (92 days)
This 37 year-old Caucasian female was hospitalized on 10/21/95 with complaints of abdominal pain and mild nausea in the lower left quadrant. After undergoing a colonoscopy and biopsies she was diagnosed with an ischemic-type colitis associated with her lupus. She was treated with IV Solu-Medrol 20mg, and was discharged on prednisone 4 days later, 10/25/95.

Patient # **23007** (356 days)
This 47 year-old Caucasian female with a history of pericarditis, arthritis, and class III nephritis was hospitalized on 2/12/97 with complaints of arthritic pain, nausea and vomiting diagnosed as a SLE flare. She received Solu-Medrol 20 I.V. every 6 hours until discharged. She was discharged after 2 days on 2/14/97 on 5 mg of prednisone.

Patient # **23009** (369 days)
This 34 year-Old Caucasian female with a history of asthmatic bronchitis and myocardial infarction experienced 2 SAEs while participating in this study.

On 12/19/98 the patient was hospitalized for an asthmatic bronchitis attack. She was treated with IV Solu-Medrol and inhalation therapy. She was discharged after 1 day on 12/20/98 on a prednisone taper (10 mg t.i.d. for two days, then 10 mg b.i.d. for two days, then 10 mg a day for two days and then 4 mg daily).

On 3/23/99 she was hospitalized for chest tightness. She was examined, had a chest X-ray and was diagnosed as having atypical chest pain. She was prescribed Prevacid, 15 mg and was discharged after one day, 3/34/99.

Patient # **25002** (Approximately 2 weeks post study)
This 44 year-old Caucasian female with a history lupus nephritis, anti-phospholipid antibody syndrome, glucose intolerance and superaventricular tachycardia has been on anticoagulant treatment throughout the study. She was hospitalized on 10/24/96 (approximately 2-weeks after discontinuing study medication (10/2/96) with gross hematuria. The patient was reported to have hematuria during the study and was advised to go to the emergency room. She waited one week before going to the ER. Her anticoagulant therapy for anti-phospholipid antibody syndrome was discontinued and she subsequently developed diplopia. A MRI was normal and it was thought the event was related to a thromboembolic event and anticoagulation was restarted. The patient was treated for active lupus nephritis.

Patient # **25003** (145 days)
This 43 year-old Hispanic female with a history of aortic stenosis (1976), anticardiolipin syndrome with retinal vein thrombosis, lupus nephritis, hypertension, pancreatitis, epilepsy, chronic endometriosis, and dysmenorrhea was hospitalized on 1/12/96 for cardiac catheterization to assess aortic stenosis. The patient's valvular disease was mildly symptomatic until October 1995 when she began to have significant symptoms including chest pain at rest, dyspnea on exertion and, lower extremity edema. She underwent a physical examination, and laboratory assessments including chest x-ray. After undergoing Cardiac catheterization assessment it was determined that the patient did not need a valve replacement at this time. She was discharged in good condition 8 days later, 1/20/96.

On 4/17/96 this patient was hospitalized for pulmonary hemorrhage. The differential diagnosis included infection, exacerbation of her underlying SLE and, bleeding/clotting diathesis. On April 28, 1996 she was discharged with the assumption that her symptoms were SLE related.

On 4/30/96 the patient called the paramedics because of chest pain. She was noted to be hypertensive and was given 1 nitroglycerine tablet on the way to the hospital. As the ambulance arrived at the hospital she suffered a cardiac arrest and could not be resuscitated. The presumed cause of death was cardiac arrest. An autopsy was performed and cause of death was determined to be a result of complications of systemic lupus erythematosus.

Patient # **25005** (# of days still pending)
This 51 year-old African American female with a history of severe diabetes mellitus and hypertension was hospitalized on 12/6/96 with complaints of left side headache, nausea, vomiting, high blood pressure and, diplopia. Symptoms had been present for approximately two weeks. She was examined and noted to be hypertensive, to have palsies of cranial nerves III and VI and to have nystagmus. A MRI revealed a left cerebellar lesion consistent with infarct. She was initially treated with heparin and the next day she improved slightly. On 12/8/96 the patient developed new left facial numbness. A CT scan revealed expansion of the previous infarct and hydrocephalus. On 12/9/96 the patient experienced respiratory compromise and underwent emergency intubation. A CT was done without change although she was noted to have left hemiparesis and worsening left extrocular muscle paralysis. She underwent emergency craniotomy, with resection of approximately half of the left side of the cerebellum in an attempt at decompression. About 12/18/96 she became febrile and broad-spectrum antibiotics were started. Additionally her blood pressure and serum glucose became labile. Because of the persistent need for intubation, she underwent tracheostomy placement. On 12/24/96 she was thought to have sinusitis. On 12/31/96, she was noted to have *clostridium difficile* toxin in the stool. On 1/1/97, she was noted to have a right lower lobe infiltrate on chest x-ray, and antibiotics were changed. She developed pseudomeningocele (with CSF leakage) and was scheduled to have this repaired on 1/16/97 when she developed hypotention thought to be related to I.V. dilantin administration for seizures. About 1/21/97 she suffered a myocardial infarction, digital ischemia and gangrene and was transferred to CCU on 1/24/97. She improved slightly, developed gram negative sepsis and meningitis. Despite vigorous efforts at treatment she died on 2/7/97.

Patient # **27001** (249 days)
This 67 year-old Caucasian female with a history of heavy smoking (quit in 1988), chronic obstructive pulmonary disease, thrombocytopenia, hemolytic anemia, lupus anticoagulant, shrinking lung syndrome, hypothyroidism, shortness of breath and wheezing was hospitalized on 11/21/95 with complaints of shortness of breath. After undergoing a physical examination, chest x-ray and laboratory assessments she was diagnosed with chronic respiratory insufficiency thought to be related to shrinking lung syndrome. On 11/25/95 a gallium scan revealed bilateral increased lung uptake, as well as increased right kidney uptake consistent with an infection. On 11/26/95 she was febrile at 103, found to have urosepsis with positive blood cultures for E. coli and was sensitive to all antibiotics tested. On 11/27/95 her urinalysis showed 100 to 200 WBCs. On 11/29/95 she was diagnosed with acute renal failure secondary to sepsis.

On 12/4/95 she was transferred to another hospital to participate in an in-patient pulmonary rehabilitation program. At the time of discharge, 1/10/96, she was able to ambulate with a front-wheeled walker.

On 2/15/96 she was hospitalized after being found unconscious at home. It was determined that she had complete heart block but no myocardial infarction. A temporary pacemaker was placed with improvement in her heart rate. She convalesced nicely and was discharged on 2/24/96

On 3/25/96 she was hospitalized with complaints of severely increasing respiratory distress, pulmonary edema, nausea and vomiting. It was noted in the emergency room that she was supposed to be taking Lasix but had been non-compliant. After undergoing a chest x-ray, EKG and laboratory tests she was diagnosed with acute congestive heart failure and chronic obstructive pulmonary disease with acute exacerbation. She was treated with Proventil, IV Lasix, procardia and Isordil.

In March of 1996 this patient was hospitalized for congestive heart failure and chronic obstructive pulmonary disease. On 5/19/96 she died due to complete respiratory distress.

Patient # **27003** (# of days still pending)
This 25 year-old Caucasian female with a history of lupus nephritis and hypertension was hospitalized 12/21/95 to undergo renal biopsy in the assessment of proteinuria and renal insufficiency. She was discharged the same day.

On 01/10/96 she started Cyclosporin 200 mg for membranous nephritis and on 3/13/96 it was lowered to 100 – 150 mg.

On 9/22/95 this patient was hospitalized for myofascial pain secondary to large breast tissue.

On 02/21/96 she was hospitalized for bilateral reduction mammoplasty. The procedure was performed on 02/26/96 followed by an unremarkable postoperative course. She was prescribed Darvocet for pain and Keflex and was discharged the same day.

Patient # **27005** (150 days)
This 54 year-old Caucasian female with a history of avascular necrosis of her right hip secondary to chronic steroid use was hospitalized on 6/18/96 to undergo a right total hip replacement (performed 6/20/96). She did well and was managed on Coumadin. She was given a Kenalog injection to control her lupus. She was transfused because of postoperative anemia and was transferred 4 days later, 6/24/96 to a nursing facility to continue rehabilitation.

Patient # **27006** (# of days still pending)
This 24 year-old Caucasian female with a history of Hashimoto's thyroiditis, inflammatory arthritis, proliferative nephritis Class III and hypertension was hospitalized for elective renal biopsy on 2/21/96 because her 24-hour urine remained in nephrotic ranges. She was diagnosed with diffuse proliferative glomerulonephritis with considerable sclerosis. She was prescribed Darvocet and discharged the same day.

On 5/16/96 this patient was hospitalized for an elective surgery; abdominal lipectomy, repair ventral hernia and excision of abdominal panniculus following a sixty-pound weight loss. She was prescribed Darvocet and discharged after 14 hours.

On 11/1/96 this patient was hospitalized with complaints of anorexia, malaise, nausea and vomiting. She was diagnosed with end-stage renal failure with uremic symptomatology and underwent placement of Gortex graft and maintenance hemodialysis started. She had kidney transplant surgery performed on01/25/97.

Patient # **27007** (244 days)
This 67 year-old Caucasian female with a history of osteoporosis, hypertension, autoimmune hemolytic anemia, deep vein thrombosis of the right lower extremity, and glomerulonephritis was hospitalized on 11/19/96 for an elective angioplasty of the right coronary artery. The patient was first diagnosed with coronary artery disease in 8/96 when she presented with complaints of progressive dyspnea.

Following removal of the arterial sheath the patient developed a large right groin hematoma, as well as significant drop in hematocrit. She was transfused with one unit of packed cells and was discharge 3 days later, on 11/22/96 with arrangements for a visiting nurse.

On 11/24/96 this patient was admitted for evaluation and treatment of severe anemia with transient hypotensive episode. Blood cultures and urinalysis was performed and she was started on broad-spectrum antibiotic coverage. She was transfused with Lasix and tolerated the transfusion well.

The patient complained of a very tender right groin and an ultrasound of the right leg was done. She was diagnosed with pseudoaneurysm in the right femoral artery and she underwent compression therapy without complication. At the time of discharge, 3 days later, the patient's hemoglobin and hematocrit were stable.

On 7/97 this patient was hospitalized for a fractured hip subsequent to a fall.

Patient # **28003** (148 days)
This 48 year-old Caucasian female presented to the emergency room on 3/15/96 with extreme joint aching, fatigue and leg pain. She was diagnosed as having a lupus flare, treated with 60 mg of prednisone and discharged 6 hours later.

Patient # **33004** (109 days)
This 41 year-old Caucasian female with a family history of peritoneal/ovarian carcinoma, was hospitalized on 5/11/98 because she recently had a cancer antigen 125 drawn which was 255 and the repeat was 288. She underwent diagnostic laparoscopy, a partial omentectomy followed by a laparoscopically assisted vaginal hysterectomy. All her excised tissue was benign and she tolerated the procedure well. She was discharged on routine pain medication and hormone replacement therapy, the next day, 5/12/98.

On 01/02/98 this patient was hospitalized with complaints of a weeklong history of cough and increasing shortness of breath for which she had been taking Biaxin. She underwent a physical exam, EKG, chest x-ray and laboratory test. The chest x-ray showed diffused interstitial disease suggestive of viral pneumonia. She was started on intravenous Rocephin in addition to her Biaxin. She improved but was still experiencing diffuse wheezing so she was switched to Cefzil and Albuterol and Atrovent treatments were initiated along with increases in her Prednisone. She was discharged two days later, 01/04/98, with an additional seven days of Cefzil along with a prednisone taper starting at 40mg.

Patient # **36007** (131 days)
This 60 year-old Caucasian female with a history of polymyositis, polymyopathy, polyneuropathy, vasculitis, fibromyalgia, thrombophlebitis, deep vein thrombosis, esophageal ulcer disease, and hypertension was hospitalized on 02/20/98 with complaints of progressive muscle weakness of her upper and lower extremities and sterile pyuria. After undergoing a physical examination, laboratory assessments, Renal ultrasound, cystoscopy, ultrasound, CT of spine and MRI of the brain. She received Solu-Medrol, one gram daily for three days, bactrim and was schedule for steroid injections. Her condition was improved at time of discharge 4 days later, 2/24/98.

Patient # **38015** (43 days days)
This 50 year-old Caucasian female with a history of chronic daily headaches, connective tissue disease, endometriosis, irritable bowel syndrome and hiatal hernia was hospitalized on 11/7/97 with complaints of severe chronic daily headaches and insomnia. During the time of this event the patient was being tapered off butalbital. After undergoing a physical examination she was diagnosed with chronic refractory migraine headache and butalbital habituation and withdrawal. She was treated with IV dihydroergotamine protocol and a

Captapress patch. In addition her amitriptyline was increased for sleep. This patient was discharged 4 days later on 11/11/97 after being headache free for 24 hours.

Patient # **40001** (227 days)
This 32 year-old Caucasian female was hospitalized on 4/3/98 for elective partial right wrist fusion surgery.

Patient # **41004** (362 days) 41 days post completion
This 39 year-old African-American female was hospitalized on 10/7/98 with complaints of neck, shoulder and head discomfort following a car accident. After undergoing chest, cervical, spinal and pelvic x-rays with no evidence of fracture, she was placed in a hard collar and discharged.

Patient # **41006** (227 days)
This 55 year-old Caucasian female was admitted for out patient surgery on 1/8/96 for repair of a dislocated left thumb. On 12/25/95 she dislocated her thumb which subsequently did not heal properly. She underwent interpositional arthroplasty with no complications.

Patient # **43002** (Approximately 233 days)
This 47 year-old Caucasian female with a long-term history of uncontrolled bleeding was hospitalized March of 98 to undergo a hysterectomy. She was discharged 3 days later and has recovered from this procedure.

Patient # **43006** (293 days)
This 43 year-old Caucasian female with a history of mitral valve prolapse, angina and anemia was hospitalized on 7/14/98 with complaints of chest pain suggestive of ischemic heart disease. She underwent an EKG, followed by a cardiac catheterization with results of trace mitral insufficiency. She was discharged 2 days later, 7/16/98.