

APPENDIX 2

Definition of Clinical Deterioration

The following conditions qualified as serious drug toxicity:

- **New onset diabetes mellitus**, defined as diabetes requiring drug therapy for ≥ 3 months
- **New gastric or duodenal ulcer**, not due to helicobacter pylori requiring hospitalization or transfusion
- **New onset hypertension**, requiring drug therapy ≥ 3 months
- **New myocardial infarction**, by EKG or enzymatic criteria
- **New steroid myopathy**
- **New elevation in serum transaminases:** AST, ALT to ≥ 8 times the upper limit of normal or a single measurement ≥ 3 times the upper limit of normal on multiple measurements over 3 months
- **New fracture and/or vertebral collapse** due to osteoporosis.

The following conditions qualified as major new or progressive organ disease, assessed by the treating physician as attributable to lupus or its treatment and occurring during study drug treatment or within 6 weeks post discontinuation of study drug treatment:

- **CNS:** CVA, transverse myelitis, retinal vascular occlusion, new onset of psychosis > 3 months, new onset of seizures refractory to therapy for at least 3 months.
- **Renal:** New onset of end stage renal disease or loss of renal function that required dialysis for at least 3 months.
- **Pulmonary:** New or worsened pulmonary hypertension and/or interstitial lung disease with reduction in diffusion capacity, mean pulmonary artery pressure and/or dyspnea at rest (NYHA Class IV).

- **Cardiovascular:** Pericarditis refractory to treatment for > 3 months or that required pericardiectomy; cardiomyopathy refractory to therapy for > 3 months with hemodynamic compromise (decreased cardiac index, left ventricular ejection fraction and/or dyspnea at rest) and/or refractory arrhythmia.
- **Gastrointestinal:** Ischemic bowel disease that required bowel resection.
- **Vasculitis:** Vasculitis that resulted in infarction (excluding vasculitis described under other organ systems).
- **Hematologic:** Thrombocytopenia that resulted in clinically significant hemorrhage with sequelae that did not resolve for at least 3 months; persistent leukopenia (WBC < 1,500) that resulted in recurrent infections without improvement in incidence of recurrent infections for at least 3 months.

The following qualified as unacceptable increase in immunosuppressive or cytotoxic therapy for lupus:

- **Drug Increases:** Any SLE-related increase in doses of concomitant methotrexate, azathioprine, or institution of new therapy with cytotoxic or immunosuppressive agents (methotrexate, azathioprine, cyclophosphamide, or cyclosporine) at any time during study drug treatment or within 6 weeks post-discontinuation of study drug treatment. Except for stress doses, daily prescribed prednisone dosage as exceeding 10 mg/day over baseline dosage within the first 2 months of participation or, through the remainder of the study, daily prednisone dose increased to more than 5 mg/day over daily baseline dose for > 2 consecutive months.

APPENDIX 3

Baseline Demographics and Characteristics (Intent to Treat Population)

| | All Patients | | All Patients, Baseline SLEDAI >2 | |
|---------------------------|------------------|-----------------------|----------------------------------|-----------------------|
| | Placebo N=192 | GL701 200 mg N=189 | Placebo N=146 | GL701 200 mg N=147 |
| Mean (median) Age | 44 (43) | 44 (45) | 44 (43) | 44 (44) |
| Caucasian | 137 (71%) | 146 (77%) | 99 (68%) | 110 (75%) |
| African-American | 33 (17%) | 22 (12%) | 27 (19%) | 18 (12%) |
| Asian | 3 (2%) | 2 (1%) | 3 (2%) | 2 (1%) |
| Hispanic | 16 (8%) | 15 (8%) | 14 (10%) | 14 (10%) |
| Other | 3 (2%) | 4 (2%) | 3 (2%) | 3 (2%) |
| Post-menopausal | 92 (48%) | 83 (44%) | 68 (47%) | 63 (43%) |
| Pre-menopausal | 100 (52%) | 106 (56%) | 78 (53%) | 84 (57%) |
| Prednisone use (mg) | 103 (54%) | 103 (55%) | 85 (58%) | 83 (56%) |
| Immunosuppressive use | 28 (15%) | 32 (17%) | 25 (17%) | 29 (20%) |
| Antimalarial use | 48 (25%) | 44 (23%) | 36 (25%) | 28 (19%) |
| Mean (median) SLEDAI | 5.8 (5.0) | 6.5 (6.0) | 7.3 (6.0) | 8.0 (8.0) |
| Mean (median) SLAM | 12.0 (12.0) | 12.2 (12.0) | 12.5 (12.0) | 12.7 (12.5) |
| Mean (median) Patient VAS | 55.4 (57.0) | 55.2 (57.0) | 55.2 (56.8) | 57.1 (58.5) |
| Mean (median) KFSS | 5.6 (5.7) | 5.5 (5.9) | 5.6 (5.7) | 5.6 (5.9) |

APPENDIX 4

Exclusions from the Per-Protocol Population

Thirty-five (35) patients were in the intent-to-treat population and not in the per-protocol population. Of these, 19 were in the GL701 group and 16 in the placebo group. These patients are described in the attached table. All but three of these 35 patients were excluded from the per-protocol patient population because they had no efficacy assessments, except at baseline. Therefore, the per-protocol population is very close to a so-called “modified intent-to-treat” population in which patients without post-baseline assessments are excluded. According to the analysis plan, such patients, without any assessments of efficacy, when analyzed in the intent-to-treat population, would by default be considered non-responders. The 3 patients with on-treatment assessments were all in the placebo group and were also excluded from the per-protocol population. One of these, patient # 18717, a non-responder, was excluded due to a major protocol violation. (She was non-compliant and did not take study drug during her first three months on study.) The other two had received less than 60 days study drug treatment, but had efficacy assessments at a termination visit. Based on the termination visit, one of these latter two was assessed as a responder, patient #43699, and the other, patient #38797, a non-responder.

Exclusions from the Per-Protocol Population

| Patient ID | Treatment | Duration on Study Drug (days) | Reason for Exclusion | Termination Reason or Comment |
|------------|-----------|-------------------------------|------------------------------|--|
| 12577 | GL701 | 31 | No post-baseline assessments | Mild vaginal bleeding |
| 15635 | GL701 | 0 | No post-baseline assessments | Wanted to be treated by homeopath |
| 15740 | GL701 | 10 | No post-baseline assessments | Abdominal bloating and worsening depression |
| 16560 | GL701 | 31 | No post-baseline assessments | Lost to Follow-up |
| 19453 | GL701 | 6 | No post-baseline assessments | Needed prohibited con medication for inflammatory bowel disease |
| 19531 | GL701 | 30 | No post-baseline assessments | Pregnant |
| 20590 | GL701 | 38 | No post-baseline assessments | Nausea, bloating, foul smelling stools |
| 21576 | GL701 | 125 | No post-baseline assessments | Lost to follow-up. Never returned for scheduled visit, so 125 days on study drug only an estimate. |
| 23726 | GL701 | 22 | No post-baseline assessments | Worsening of pre-existing rash, alopecia, fatigue, pleuritic chest pain |
| 35710 | GL701 | 10 | No post-baseline assessments | Increase in shoulder and arm pain, which preceded study |
| 35711 | GL701 | 8 | No post-baseline assessments | Wanted to participate in another study |
| 36513 | GL701 | 24 | No post-baseline assessments | Nausea and acne |
| 36570 | GL701 | 48 | No post-baseline assessments | Weight gain |
| 38662 | GL701 | 0 | No post-baseline assessments | Lost to follow-up |
| 43452 | GL701 | 50 | No post-baseline assessments | Moved |
| 43555 | GL701 | 69 | No post-baseline assessments | Lack of efficacy |
| 43616 | GL701 | 35 | No post-baseline assessments | Delusional thoughts and inappropriate behavior, which preceded study |

| Patient ID | Treatment | Duration on Study Drug (days) | Reason for Exclusion | Termination Reason or Comment |
|-------------------|------------------|--------------------------------------|------------------------------|--------------------------------------|
| 43752 | GL701 | 82 | No post-baseline assessments | Depression |
| 45585 | GL701 | 74 | No post-baseline assessments | Pregnant |
| 13418 | Placebo | 46 | No post-baseline assessments | Cholecystectomy |
| 13420 | Placebo | 7 | No post-baseline assessments | Depression, poor efficacy |
| 15472 | Placebo | 21 | No post-baseline assessments | Hot flashes |
| 15517 | Placebo | 0 | No post-baseline assessments | Lost to follow-up |
| 15633 | Placebo | 100 | No post-baseline assessments | Dysfunctional bleeding |
| 18717 | Placebo | 365 | Major protocol violation | Did not take drug for first 90 days |
| 21409 | Placebo | 78 | No post-baseline assessments | Septicemia |
| 25464 | Placebo | 38 | No post-baseline assessments | Lost to follow-up |
| 35712 | Placebo | 5 | No post-baseline assessments | Suicide |
| 38501 | Placebo | 1 | No post-baseline assessments | Lost to follow-up |
| 38784 | Placebo | 106 | No post-baseline assessments | Scheduling conflicts |
| 38797 | Placebo | 47 | Less than 60 days study drug | Moved |
| 40630 | Placebo | 92 | No post-baseline assessments | Fluid retention, mood swings, acne |
| 43699 | Placebo | 19 | Less than 60 days study drug | Increased fatigue |
| 46730 | Placebo | 83 | No post-baseline assessments | Non-compliant |
| 48817 | Placebo | 80 | No post-baseline assessments | Sudden Death |

APPENDIX 5

Responders: Intent to Treat Population (GL95-02)

| Variable | ITT | | | ITT Baseline SLEDAI > 2 | | |
|---------------------------------------|------------------|----------------|-------------|----------------------------|----------------|-------------|
| | Placebo N=192 | GL701 N=189 | P-value | Placebo N=146 | GL701 N=147 | P-value |
| | | | Improvement | | | Improvement |
| Responders (without window) | 52 | 58 | 0.4378 | 42 | 55 | 0.1166 |
| | 27.1% | 30.7% | 13.3% | 28.8% | 37.4% | 29.9% |
| Responders (pre-defined window) | 81 | 97 | P = 0.074 | 65 | 86 | P = 0.017 |
| | 42.2% | 51.3% | 21.6% | 44.5% | 58.5% | 31.5% |
| Responders (3% window)* | 57 | 75 | P = 0.041 | 47 | 71 | P = 0.005 |
| | 29.7% | 39.7% | 33.7% | 32.2% | 48.3% | 50.0% |
| Responders (5% window)* | 63 | 77 | P = 0.109 | 50 | 72 | P = 0.011 |
| | 32.8% | 40.7% | 24.1% | 34.3% | 49.0% | 42.9% |
| Responders (10% window)* | 70 | 91 | P = 0.021 | 56 | 84 | P = 0.001 |
| | 36.5% | 48.2% | 32.1% | 38.4% | 57.1% | 48.7% |

* Baseline mean + 3%, 5%, or 10% of patient's baseline mean

Note: Patients missing all 4 post-baseline variables were considered as non-responders in the ITT analysis.

Survival Analysis for First Definite Flare: Intent to Treat Population (GL95-02)

| | Intent to Treat, Baseline SLEDAI >2* | | Intent to Treat** | |
|--|---|-----------------------|-------------------|-----------------------|
| | Placebo N=146 | GL701 200 mg N=147 | Placebo N=192 | GL701 200 mg N=189 |
| Number of Patients Experiencing Definite Flare | 50 (34.2%) | 36 (24.5%) | 57 (29.7%) | 45 (23.8%) |

*P-value (p=0.0967) is from a log-rank test for time to first definite flare.

**P-value (p=0.2657) is from a log-rank test for time to first definite flare.

Patients were followed up for 7 days after their last medication date.

**Mean Changes in Scoring Instruments from Baseline: Intent to Treat Population
(GL95-02)**

| Variable | Intent to Treat, Baseline SLEDAI > 2 | | Intent to Treat | |
|---------------|--------------------------------------|-----------------------|------------------|-----------------------|
| | Placebo N=146 | GL701 200 mg N=147 | Placebo N=192 | GL701 200 mg N=189 |
| SLEDAI | -2.5 (N=134) | -3.2 (N=132) | -1.7 (N=178) | -2.2 (N=170) |
| Patient VAS | -3.0 (N=134) | -7.2 (N=131) | -4.5 (N=178) | -6.2 (N=169) |
| Physician VAS | -4.3 (N=134) | -5.4 (N=131) | -5.1 (N=178) | -5.6 (N=169) |
| KFSS | -0.3 (N=134) | -0.3 (N=131) | -0.4 (N=178) | -0.3 (N=169) |
| SLAM | -2.7 (N=134) | -3.2 (N=132) | -2.7 (N=178) | -3.1 (N=170) |
| SLICC | -0.1 (N=104) | -0.1 (N=97) | -0.1 (N=140) | -0.1 (N=128) |
| SF36 - MCS | 1.6 (N=132) | 2.3 (N=129) | 1.8 (N=175) | 2.6 (N=166) |
| SF36 - PCS | 0.9 (N=132) | 1.9 (N=129) | 1.7 (N=175) | 1.8 (N=166) |

APPENDIX 6

Patients Reclassified as Responders When a 3% of the Patient's Baseline Value "Window" Is Used

| ID | SLEDAI* | | Patient VAS* | | SLAM* | | KFSS* | |
|-------|----------|--------------------|--------------|--------------------|----------|--------------------|----------|-------------------------|
| | Baseline | Change | Baseline | Change | Baseline | Change | Baseline | Change |
| 3429 | 5.00 | -2.47 | 35.00 | <i>0.97</i> | 12.50 | -6.02 | 5.39 | -0.30 |
| 3431 | 5.00 | <i>0.08</i> | 58.00 | -5.62 | 14.00 | -2.00 | 5.94 | -0.10 |
| 15414 | 10.00 | -7.75 | 56.00 | -13.67 | 12.00 | -3.25 | 5.39 | <i>0.07</i> |
| 15636 | 8.00 | -3.55 | 52.00 | <i>0.10</i> | 16.00 | -4.39 | 5.11 | -0.52 |
| 18724 | 8.00 | -4.00 | 65.50 | <i>0.16</i> | 13.50 | -3.74 | 7.00 | -0.14 |
| 18767 | 4.00 | -4.00 | 56.50 | -9.50 | 10.50 | -3.98 | 5.22 | <i>0.11</i> |
| 19498 | 10.00 | -2.89 | 77.50 | -0.52 | 12.00 | <i>0.17</i> | 5.50 | -1.14 |
| 28807 | 14.00 | -10.50 | 61.50 | <i>1.21</i> | 11.00 | -6.00 | 5.89 | -0.52 |
| 35654 | 2.00 | -2.00 | 77.00 | -10.59 | 11.50 | -2.30 | 6.00 | <i>0.03</i> |
| 36525 | 4.00 | -0.49 | 64.50 | -27.50 | 13.00 | -4.05 | 4.72 | <i>< 0.01</i> |
| 36571 | 7.00 | -3.01 | 65.50 | -5.13 | 7.50 | -1.83 | 6.06 | <i>0.02</i> |
| 37496 | 8.00 | -0.99 | 35.50 | -5.61 | 9.00 | -2.43 | 3.06 | <i>0.05</i> |
| 38402 | 12.00 | -11.54 | 60.00 | -11.31 | 11.50 | -0.12 | 6.72 | <i>0.12</i> |
| 38404 | 4.00 | <i>0.11</i> | 63.00 | -27.95 | 15.00 | -1.23 | 4.78 | -0.91 |
| 38606 | 4.00 | -0.45 | 63.50 | -11.28 | 14.00 | <i>0.42</i> | 6.50 | -0.09 |
| 38734 | 4.00 | 0.00 | 51.50 | -5.50 | 11.00 | -2.50 | 5.94 | <i>0.17</i> |
| 41535 | 12.00 | -2.01 | 70.00 | -22.68 | 10.00 | <i>0.24</i> | 5.89 | -1.62 |
| 45588 | 9.00 | -4.13 | 71.00 | <i>0.31</i> | 15.00 | -1.52 | 6.61 | -0.29 |
| 45598 | 16.00 | -9.24 | 75.00 | <i>0.66</i> | 16.00 | -2.13 | 5.94 | -0.71 |
| 45600 | 12.00 | -8.00 | 53.00 | -1.00 | 14.50 | -3.50 | 5.94 | <i>0.06</i> |
| 49802 | 6.00 | -4.69 | 78.50 | -10.28 | 11.50 | -3.93 | 6.67 | <i>0.13</i> |
| 49803 | 4.00 | -3.50 | 68.00 | -5.79 | 10.00 | -0.03 | 5.89 | <i>0.05</i> |

****BOLDED ITALICIZED*** numbers indicate change from baseline for individual scores within the 3% window that would lead to re-classification from non-responder to responder.

APPENDIX 7

Early Termination due to Safety Concerns, Adverse Events or Death All randomized patients from GL94-01 and GL95-02

| Patient | Treatment Group | Reason for Early Termination |
|---------|-----------------|--|
| 18141 | Placebo GL94-01 | Hospitalized for pneumonia |
| 19131 | Placebo GL94-01 | Menometrorrhagia |
| 27206 | Placebo GL94-01 | Large decubiti, bactermia, hemolytic anemia |
| 43699 | Placebo GL95-02 | Fatigue increased |
| 15472 | Placebo GL95-02 | Hot flashes |
| 40630 | Placebo GL95-02 | Acne, mood swings, fluid retention |
| 38736 | Placebo GL95-02 | Rash |
| 3507 | Placebo GL95-02 | Hepatitis |
| 43602 | Placebo GL95-02 | Weight gain |
| 43538 | Placebo GL95-02 | Lupus flare - skin rash |
| 25462 | Placebo GL95-02 | Weight gain |
| 43614 | Placebo GL95-02 | Suicidal depression |
| 36638 | Placebo GL95-02 | Pregnancy |
| 15634 | Placebo GL95-02 | Pseudotumor cerebri |
| 20511 | Placebo GL95-02 | Pulmonary HT and fibrosis |
| 21409 | Placebo GL95-02 | Septicemia |
| 33444 | Placebo GL95-02 | Chest pain due to coronary artery spasm |
| 35712 | Placebo GL95-02 | Suicide |
| 36685 | Placebo GL95-02 | Carcinoma of the lung |
| 37495 | Placebo GL95-02 | Suicide |
| 48817 | Placebo GL95-02 | Sudden death, possibly due to arrthmia |
| 15295 | 100 mg GL94-01 | Viral Hepatitis C |
| 16191 | 100 mg GL94-01 | Nausea and hip pain |
| 17176 | 100 mg GL94-01 | Vasculitis |
| 22169 | 100 mg GL94-01 | Hirsutism/acne |
| 3152 | 200 mg GL94-01 | GI bleed secondary to NSAIDs |
| 14109 | 200 mg GL94-01 | Headache, nausea, back pain, spasm |
| 21197 | 200 mg GL94-01 | Decreased WBCs, increased LFTs |
| 21201 | 200 mg GL9401 | Sores on buttock |
| 24275 | 200 mg GL94-01 | Worsening rash, alopecia, purpura, increased prednisone dose |
| 28301 | 200 mg GL94-01 | Facial dermatitis |
| 35710 | 200 mg GL95-02 | Myalgias |
| 15740 | 200 mg GL95-02 | Depression/abdominal bloating |
| 36513 | 200 mg GL95-02 | Nausea/acne |
| 12577 | 200 mg GL95-02 | Vaginal bleeding |

| Patient | Treatment Group | Reason for Early Termination |
|----------------|------------------------|--|
| 43616 | 200 mg GL95-02 | Psychosis/delusional thoughts |
| 20590 | 200 mg GL95-02 | Nausea/bloating, foul smelling stools |
| 36570 | 200 mg GL95-02 | Weight gain |
| 20684 | 200 mg GL95-02 | Metrorrhagia |
| 43752 | 200 mg GL95-02 | Dyspepsia |
| 25461 | 200 mg GL95-02 | Depression |
| 38403 | 200 mg GL95-02 | Acne |
| 19530 | 200 mg GL95-02 | Menorrhagia |
| 35653 | 200 mg GL95-02 | Hirsutism |
| 46695 | 200 mg GL95-02 | Syncope |
| 18670 | 200 mg GL95-02 | Worsening alopecia |
| 13761 | 200 mg GL95-02 | Acne/hirsutism |
| 43700 | 200 mg GL95-02 | Acne/hirsutism |
| 45600 | 200 mg GL95-02 | Acne |
| 15416 | 200 mg GL95-02 | Pulmonary edema |
| 38716 | 200 mg GL95-02 | Abdominal pain |
| 25595 | 200 mg GL95-02 | Acne |
| 33705 | 200 mg GL95-02 | Acne/hirsutism |
| 18618 | 200 mg GL95-02 | Mood change/facial hair growth |
| 3431 | 200 mg GL95-02 | Depression |
| 43554 | 200 mg GL95-02 | Fluid retention, insomnia, leg pain, renal deterioration |
| 38631 | 200 mg GL95-02 | Acne/hirsutism |
| 32468 | 200 mg GL95-02 | Weight gain |
| 36640 | 200 mg GL95-02 | Mild depression |
| 38421 | 200 mg GL95-02 | Epigastric tenderness |
| 43744 | 200 mg GL95-02 | Breast mass (benign on biopsy) |
| 41440 | 200 mg GL95-02 | Arthritis/hirsutism/oily skin |

APPENDIX 8

Narratives for Patients that Experienced a Clinically Significant Increase in Proteinuria

Patient 27208 (Study GL94-01, placebo): This patient had pre-existing renal disease and had undergone a renal biopsy prior to study. Her 24-hour urine protein increased from 1327 at baseline to 5067 mg/24 hours at the last on-treatment visit. Baseline C3 was 67 mg/dl; C4 was 10 mg/dl (nl \geq 12 mg/dl). During the study, in addition to progressive proteinuria, new hematuria developed (0 baseline; 7 at last visit). Due to her progressive renal disease, she underwent another kidney biopsy during the study which revealed focal proliferative lupus glomerulonephritis, and she was treated with cyclophosphamide. She completed 7 months of study medication. However, her serum creatinine was stable, 1.1 at both baseline and last visit.

Patient 14483 (Study GL95-02, placebo): Her 24 hour urine protein increased from 1500 mg at baseline to 4200 mg/24 hours at the last on-treatment visit. Adverse events of proliferative glomerulonephritis and nephrotic syndrome were reported. She was treated with cyclophosphamide and terminated study early. She developed new hematuria, with 27 RBC/hpf at last visit. Her serum creatinine increased from 1.1 to 1.3 at her last on-treatment visit. However, her serum creatinine rose to 9.2 three months later, approximately 6 weeks following end of treatment.

Patient 20511 (Study GL95-02, placebo): Her 24 hour urine protein increased from 2743 mg at baseline to 4700 mg/24 hours at the last on-treatment visit. Increased pitting edema due to active nephritis was noted as an adverse event. A kidney biopsy on treatment demonstrated lupus proliferative glomerulonephritis, which was treated with steroids and azathiaprine. She was subsequently hospitalized for refractory hypertension and pulmonary hypertension. She had a final hospitalization for acute shortness of breath, and died of cardiac arrest. Serum creatinine rose during study from 1.1 at baseline to 1.5 at final visit.

Patient 38605 (Study GL95-02, placebo): Her 24 hour urine protein increased from 1500 mg at baseline to 4200 mg/24 hours at the last on-treatment visit. An adverse event of proteinuria was reported and she was treated with increased corticosteroids for her proteinuria. However, her serum creatinine only increased from 0.9 to 1.2 at end of treatment. She completed 12 months of study medication.

Patient 30265 (Study GL94-01, GL701 100 mg): Her 24 hour urine protein increased from 3498 mg at baseline to 9713 mg/24 hours at the last on-treatment visit. Hematuria was noted during the study with baseline 0 and last visit of 16 RBC/hpf. Creatinine increased from 1.1 at baseline to 3.0 at last visit. Nephrotic syndrome was noted as an adverse event and she was withdrawn from the study to initiate treatment with cyclophosphamide.

Patient 13103 (Study GL94-01, GL701 200 mg): Her 24 hour urine protein increased from 4794 mg at baseline to 10,884 mg/24 hours at the last on-treatment visit. Baseline C3 was low at 81 mg/dl while C4 was 14 mg/dl; at last visit they were 58 and 15 mg/dl. Creatinine rose from 1.3 at baseline to 1.8 mg/dl at last visit. This patient was withdrawn from the study to undergo treatment with cyclophosphamide.

Patient 19454 (Study GL95-02, GL701 200 mg): Her 24 hour urine protein increased from 656 mg at baseline to 11423 mg/24 hours at the last on-treatment visit. C3 and C4 complement were both low at baseline with C3 of 52 mg/dl and C4 of 9 mg/dl. Both remained low with last visit values of 45 and < 10 mg/dl. Serum creatinine increased from 1.3 mg/dl at baseline to 1.9 mg/dl at last visit. Blood cells in urine increased from 0 at baseline to 42/hpf at last visit.

Patient 20770 (Study GL95-02, GL701 200 mg): This patient had undergone a renal biopsy prior to entering into the study. Her 24 hour urine protein increased from 2329 mg at baseline to 10415 mg/24 hours at the last on-treatment visit. C3 complement at baseline was low at 57 mg/dl while C4 was normal at 12 mg/dl. At last visit, C3 and C4 were 34 and <10 mg/dl, respectively. Urine RBCs increased from 2/hpf at baseline to 19/hpf at last visit. She experienced a renal flare during the study and required treatment with mycophenolate mofetil (Cellcept) at study termination. However, her serum creatinine was 0.7 at baseline, and 0.9 at the on treatment visit.

Patient 23485 (Study GL95-02, GL701 200 mg): Her 24 hour urine protein increased from 527 mg at baseline to 1090 mg/24 hours at the last on-treatment visit. C3 at baseline was 84 mg/dl, C4 was 16 mg/dl. At last visit, they were 79 and 13 mg/dl. Her serum creatinine was 1.2 at baseline, and 1.0 at the on treatment visit. The patient was terminated from study drug prematurely in order to undergo treatment with cyclophosphamide for lupus nephritis.

Patient 36514 (GL701 200 mg, Study GL95-02): Her 24 hour urine protein increased from 1319 mg at baseline to 2574 mg/24 hours at on-treatment visit. Serum creatinine was 1.6 mg/dl at baseline and 1.8 mg/dl at last visit. She was hospitalized, after 8 months on study, for a renal

biopsy which revealed focal proliferative glomerulonephritis. The diagnosis at that time was labile hypertension and chronic renal failure. Her serum creatinine during the hospitalization ranged from 2.2 to 2.6 mg/dl; her creatinine clearance was 53.3. Study drug was discontinued to allow treatment with increased steroids and immunosuppressives.

Patient 38445 (Study GL95-02, GL701 200 mg): Her 24 hour urine protein increased from 2420 mg at baseline to 4648 mg/24 hours at the last on-treatment visit. Her corticosteroid dose was increased because of the proteinuria. However, her serum creatinine was stable, 1.1 at both baseline and last visit. Serum C3 decreased from 87 to 60. She did not complete 12 months study medications.