

Errata

We regret that some errors were inadvertently made in the original FDA briefing documents. We would like to issue the following corrections, which are bolded for clarity. Please substitute these corrected items in your FDA briefing document.

1. Table 3.2.4A

Table 3.2.4A. Baseline Serum Creatinine of Study GS-98-435

	Treatment Cohort ¹			
	1A (n = 117)	2A (n = 12)	3A (n = 67)	Total (n = 196)
Baseline serum creatinine				
Grade 1 (1.5 - 2.0 mg/dL)	17 (15%)	3 (25%)	11 (16%)	31 (16%)
Grade 2 (2.1 - 3.0 mg/dL)	2 (2%)	0	6 (9%)	8 (4%)
Grade 3 (3.1 - 6.0 mg/dL)	1 (< 1%)	0	2 (3%)	3 (2%)
Grade 4 (> 6.0 mg/dL)	0	0	0	0
Total	20 (17%)	3 (25%)	19 (31%)	42 (22%)
	1B (n = 46)	2B (n = 2)	3B (n = 80)	Total (n = 128)
Baseline serum creatinine				
Grade 1	1 (2%)	0	3 (4%)	4 (3%)
Grade 2	0	0	0	0
Grade 3	0	0	1 (1%)	1 (< 1%)
Grade 4	0	0	2 (2%)	2 (2%)
Total	1 (2%)	0	6 (7%)	7 (5%)

¹ Cohort 1: adequate renal, hepatic, and hematologic function at baseline; Cohort 2: patients from study GS-99-451i; Cohort 3: inadequate renal, hepatic, hematologic, and other condition at baseline; Subcohort A: post-liver transplantation patients; Subcohort B: patients waitlisted for a liver transplant.

2. Table 3.2.4B

Table 3.2.4B. Incidence of Any Increased Serum Creatinine to ≥ 0.3 mg/dL from Baseline and Hypophosphatemia to < 2.0 mg/dL of Study GS-98-435 (as of Safety Update Cutoff Date)

	Treatment Cohort ¹			
	1A (n = 117)	2A (n = 12)	3A (n = 67)	Total (n = 196)
Creatinine increased				
Grade 1 (1.5 - 2.0 mg/dL)	34 (29%)	7 (58%)	18 (29%)	59 (31%)
Grade 2 (2.1 - 3.0 mg/dL)	13 (13%)	1 (8%)	13 (21%)	27 (14%)
Grade 3 (3.1 - 6.0 mg/dL)	1 (1%)	0	4 (6%)	5 (3%)
Grade 4 (> 6.0 mg/dL)	3 (3%)	0	1 (2%)	4 (2%)
0.3 to < 0.5 mg/dL ¹	22 (22%)	2 (18%)	7 (13%)	31 (18%)
≥ 0.5 mg/dL ¹	24 (24%)	3 (27%)	17 (30%)	44 (26%)
Hypophosphatemia				
Grade 1 (2.0-2.4 mg/dL)	10 (10%)	4 (36%)	5 (9%)	19 (11%)
Grade 2 (1.5-1.9 mg/dL)	5 (5%)	1 (9%)	0	6 (4%)
Grade 3 (1.0-1.4 mg/dL)	0	0	1 (2%)	1 (1%)
Grade 4 (< 1.0 mg/dL)	0	0	0	0
	1B (n = 42)	2B (n = 2)	3B (n = 59)	Total (n = 103)
Creatinine increased				
Grade 1	2 (5%)	0	6 (10%)	8 (6%)
Grade 2	1 (2%)	0	5 (8%)	0
Grade 3	2 (5%)	0	3 (5%)	2 (2%)
Grade 4	0	0	1 (2%)	4 (3%)
0.3 to < 0.5 mg/dL ²	4 (10%)	0	3 (5%)	7 (7%)
≥ 0.5 mg/dL ²	7 (17%)	0	12 (20%)	19 (18%)
Hypophosphatemia				
Grade 1	2 (5%)	0	5 (8%)	7 (7%)
Grade 2	2 (5%)	1 (50%)	4 (7%)	7 (7%)
Grade 3	1 (2%)	0	1 (2%)	2 (2%)
Grade 4	0	0	0	0

¹ Cohort 1: adequate renal, hepatic, and hematologic function at baseline; Cohort 2: patients from study GS-99-451i; Cohort 3: inadequate renal, hepatic, hematologic, and other condition at baseline; Subcohort A: post-liver transplantation patients; Subcohort B: patients waitlisted for a liver transplant.

² Change from baseline

3. Table 3.2.4C

- The “n” in the header of column 3A is **67** (instead of 62).
- The total “n” is **196** (instead of 191).

4. Table 3.2.4D

The summation of patients on the line “Normal at baseline, n” should read **101** (instead of 116).

5. Page 20

Please note the following changes:

“By week 96, **15** patients (**28%**) by K-M estimate) in subcohort B, 5 (26%) in cohort 1B, none in cohort 2B, and 10 (30%) in cohort 3B, developed serum creatinine increases ≥ 0.5 mg/dL above the baseline.”

6. Page 21

Please note the following change:

“By week 96 of study 435, 26 patients (**28%** by K-M estimate) in subcohort A developed serum creatinine increase to ≥ 0.5 mg/dL above the baseline.”

7. Page 26

The case described in **Appendix A** under Bullet 2: “A 43-year-old white male on the waiting list for liver transplant started adefovir 10 mg daily on October 17, 2000...” should have been included in **Appendix B**. This case serves to illustrate that the two acute renal failure episodes in December 2000 and January 2001 were, in our opinion, more likely due to the ongoing disease processes at the time, rather than secondary to adefovir treatment.

8. Page 25

Gilead Sciences had provided corrected data on the patient listed under Bullet 1. The laboratory testing on November 27, 2000, revealed a plasma ammonia level of **248** $\mu\text{g/dL}$.