

**Errata to the FDA Briefing Document
Tecovirimat NDA 208627 Advisory Committee Meeting
May 1, 2018**

Page 72—Text Correction

Original Text:

The proposed dose of tecovirimat, 600 mg twice daily, will provide C_{min} exposures in excess (7.8-fold higher) of those demonstrated to be efficacious in the NHP model.

Revised Text:

The proposed dose of tecovirimat, 600 mg twice daily, will provide C_{min} exposures in excess (6.6-fold higher) of those demonstrated to be efficacious in the NHP model.

Page 72, Table 17—Table Correction

Original Table:

Table 17: Geometric Mean of Non-Compartmental Exposures in NHPs and Humans

Comparisons	Treatment Day	C _{max} (ng/mL)	C _{min} (ng/mL)	C _{avg} (ng/mL)	AUC ₀₋₂₄ (ng h/mL)
Human 600 mg BID	1 (first dose)	1516	477	875	20879
NHP 10 mg/kg		749	158	318	7629
Human to NHP Ratio (Unbound Ratio)		2.0 (3.3)	3.0 (4.9)	2.8 (4.5)	2.7 (4.4)
Human 600 mg BID	14 (steady state)	2106	587	1207	29131
NHP 10 mg/kg		1403	143	569	13650
Human to NHP Ratio (Unbound Ratio)		1.5 (2.4)	4.1 (6.7)	2.1 (3.4)	2.1 (3.5)

BID=twice daily, NHP=non-human primate

Revised Table:

Table 17: Geometric Mean of Non-Compartmental Exposures in NHPs and Humans

Comparisons	Treatment Day	C _{max} (ng/mL)	C _{min} (ng/mL)	C _{avg} (ng/mL)	AUC ₀₋₂₄ (ng.h/mL)
Human 600 mg BID	1 (first dose)	1591	560	924	25876
NHP 10 mg/kg		809	193	338	8110
Human to NHP Ratio (Unbound Ratio)		2.0 (3.2)	2.9 (4.7)	2.7 (4.4)	3.2 (5.2)
Human 600 mg BID	14 (steady state)	2209	690	1270	30632
NHP 10 mg/kg		1444	169	598	14352
Human to NHP Ratio (Unbound Ratio)		1.5 (2.5)	4.1 (6.6)	2.1 (3.4)	2.1 (3.5)

KEY: BID = twice daily, NHP = non-human primate