Errata to SIGA Technologies, Inc. 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

Page 75—Text Correction

Original Text:

8.13.5 E-IND NO. 116,039
SIGA provided tecovirimat for treatment of a 19-year-old male patient with acute myeloid leukemia who had been exposed to the virus through the military smallpox vaccine. Tecovirimat 600 mg twice daily was administered for approximately 2 months. The patient also received 2 doses of Vaccinia Immune Globulin Intravenous (Human). The patient was reported to have tolerated the extended course of tecovirimat well. Information on AEs with an onset after tecovirimat treatment initiation was not provided.

Corrected Text:

8.13.5 E-IND NO. 116,039
SIGA provided tecovirimat therapy to a 19-year-old male patient who developed complications following administration of live vaccinia vaccination and was subsequently diagnosed with acute myeloid leukemia. Tecovirimat 600 mg twice daily was administered for approximately 2 months. The patient also received 3 doses of Vaccinia Immune Globulin Intravenous (Human). The patient was reported to have tolerated the full course of tecovirimat without any adverse reactions to tecovirimat.