

Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) Meeting

April 15, 2021

*Errata – FDA Briefing Document*

1. Page 39, Section 7.3.4, in the third sentence of the paragraph under “Adverse Events of Special Interest,” change, “An additional three events were left ventricular hypertrophy, nausea and vomiting requiring hospitalization and lymphoproliferative disorder of the lacrimal gland,” to “An additional three events were left ventricular hypertrophy, nausea and vomiting requiring hospitalization and squamous cell carcinoma.”
2. Page 40, Section 7.3.4., under Table 26, in the first sentence under Table 26 change, “Fourteen (14) subjects (46.7%) had an adverse event of neoplasm,” to “Thirteen (13) subjects (43.3%) had an adverse even of neoplasm.”
3. Page 40, Section 7.3.4, under Table 26, in the second sentence change, “Table 26 lists the 13 cancers attributed to 9 subjects up to 10 years after the first transplant,” to “Table 26 lists the 12 cancers attributed to 9 subject up to 10 years after the first transplant.”