

FDA Briefing Document

Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee

January 16, 2019

Errata to the FDA Briefing Materials

1. Page 15, Table 2: The absolute risk reduction for hip fracture, month 12 should be 0.3 instead of 0.9.
2. Page 20, Table 7: Death, n (%) in the romosozumab arm of trial 20110142 should be 30 (1) instead of 30 (2).
3. Page 38, 4th line of the last paragraph should read:
“...dose of romosozumab at approximately 32- and 210-fold clinical exposure at the 210 mg monthly...” instead of
“...dose of romosozumab at approximately 32- and 21-fold clinical exposure at the 210 mg monthly...”
4. There are other single patient accounting differences in the document related to changes in trial 20070337 at the final analysis period compared to trial 20070337 submitted and reviewed during the first review cycle. These changes remain under review and do not materially impact the outcomes for discussion.