

ERRATA to FDA Briefing Document
Cardiovascular and Renal Drugs Advisory Committee Meeting
NDA 216951
October 26, 2022

1. Section 3.1.2. page 15, Second paragraph, first line under Figure 1- Delete the following text: “subjects who were ESA naïve”.
2. Section 3.1.2 page 15, Fourth paragraph Replace “every 2 days” with “three times weekly”.
3. Section 3.1.2, page 17, Table 3 top of page, subsection - ESA Users, row Intermediate dose ASCEND-D (second column) replace “4mg” with “6 or 8 mg” and row High dose replace “4 mg” with “12 mg”.
4. Section 3.1.3, page 18, Table 4: Baseline Demographics of ASCEND-ND, ITT Population: For the row entitled urine albumin creatinine ratio replace “212.6” with “212.7”; for row entitled Ferritin replace “448” with “449”; for row entitled IV oral use replace “oral” with “iron”; History of stroke row is listed twice- delete duplicate row.
6. Section 3.1.3, page 19, Table 5: for row Ferritin replace “975” with “976”.
7. Section 3.1.4, page 20, Table 6: for row Completed Study replace “1837” with “1873”.
8. Section 3.1.4, page 21: Table 7: Title should read “Drug Exposure in ASCEND-ND, Safety Population”.
9. Section 3.1.4.2, page 21: second paragraph replace “N=2864” with “N=2964”.
10. Section 3.1.4.2, page 22: Table 9: Title should read “ Drug Exposure in ASCEND-D, Safety Population”.
11. Section 3.1.5, page 23, Table 10: row “The adjusted mean treatment difference” replace “0.00” with “0.08”.
12. Section 3.1.5, page 23, Table 10: ASCEND-D column: replace “Darbepoetin alfa” with “ESA”.
13. Section 3.1.5, page 23, Table 10: last footnote replace “darbepoetin group” with “ESA group”.
14. Section 3.1.5, page 23, Table 10: Delete the phrase “dialysis start manner”.
15. Section 3.1.5, page 24: Top of page: Replace the sentence that starts with the “The use of rescue therapy ... with the following sentence “The use of rescue therapy for anemia, i.e., intravenous iron, and transfusions was also evaluated and was balanced between arms in ASCEND-D (Table 12) but was lower in the daprodustat arm in ASCEND-ND (Table 11).”

16. Section 3.1.5, page 26: First paragraph, replace the last sentence that starts with “Rescue therapy use ... with the following sentence “Rescue therapy use including intravenous iron and transfusion was similar between treatment arms in ASCEND-D; however fewer patients required rescue in the daprodustat arm in ASCEND-ND.”
17. Section 3.2.2.1, page 28, Table 13: row infection replace “4.7%” with “4.6%”.
18. Section, 3.2.2.1, page 28, Table 13: row Non-CV death, Darbepoetin column replace “7.7%” with “7.6%”
19. Section 3.2.2.1, page 28, Table 13 and page 29, Table 14: replace “Undetermined” with “Unknown”.
20. Section 3.2.3.2, page 36, Figure 4: CV MACE results should be revised to “CV MACE for daprodustat 6.15 and CV MACE darbepoetin 5.56”.
21. Section 3.2.3.6, page 40, second paragraph replace “Table 22” with “Table 24”.
22. Section 5.1.1.2.1, page 45 Table 20, row fatal and non-fatal stroke, replace “[1.9]” with “[1.5]”.
23. Section 5.1.2.1, page 50: replace “50”with “8”.
24. Section 5.1.2.3, page 56: replace “gastrointestinal bleed’ with “gastric erosions”.
25. Section 5.1.2.3, page 56, Figure 14: the figure title should read “Time to First TESAE for gastric erosion, ASCEND-ND and ASCEND-D, ITT”.