

Erratum to FDA Briefing Document
Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
November 14, 2019

This erratum contains corrections to the FDA briefing information for the November 14, 2019 EMDAC Meeting. The corrections are minor and are not expected to impact how the committee interprets the data and/or impact the committee's discussions/vote.

1. On Page 18, the first paragraph:

“... CV Risk Category 2 (planned to be 30% of enrolled patients) which included patients aged 55 years and older ...”

Should be revised to read (revision in bold and underlined):

“... CV Risk Category 2 (planned to be 30% of enrolled patients) which included patients aged **50** years and older ...”

2. On Page 24, the second to last paragraph:

“Approximately 41% had diabetes mellitus, and over 86% had hypertension.”

Should be revised to read:

“Approximately **58**% had diabetes mellitus, and over 86% had hypertension.”

3. On Page 41, the first full paragraph:

“CV Risk category was a stratification variable used in hazard ratio comparisons between treatment arms, but evaluation of outcomes in the Risk Categories was not prespecified.”

Should be revised to read:

“CV Risk category was a stratification variable used in hazard ratio comparisons between treatment arms. Evaluation of outcomes in the Risk Categories **was prespecified as an exploratory analysis.**”

4. On Pages 42 and 43, the header for Table 21, Risk Category 1:

N=5875

Should be revised to read:

N=5785

5. On Page 71, the second to last sentence:

“Even a substantial interaction between aspirin and mineral oil or between aspirin and mineral oil would have negligible effects on clinical antiplatelet activity of either drug.”

Should be revised to read:

“Even a substantial interaction between aspirin and mineral oil or between clopidogrel and mineral oil would have negligible effects on clinical antiplatelet activity of either drug.”