Erratum to FDA Briefing Document

Endocrinologic and Metabolic Drugs Advisory Committee Meeting

January 17, 2019

This erratum contains corrections to FDA's briefing information for the January 17, 2019, Endocrinologic and Metabolic Drugs Advisory Committee Meeting. At this meeting the committee will discuss the new drug application (NDA) 210934 for sotagliflozin oral tablet, sponsored by sanofi-aventis U.S. LLC for the proposed indication: adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus.

1) **On page 33, last paragraph, last sentence:**

"Formal testing was to stop at an endpoint for which a p-value exceeded 0.025 for one of two parallel tests."

Should be revised to read (change bolded and underlined)

"Formal testing **for a specific sotagliflozin dose group** was to stop at an endpoint for which a p-value exceeded 0.025 **for the corresponding test in that dose group**."

2) **On page 44, second paragraph, starting with the third sentence to the end of the fourth paragraph:**

"In study 309, the sotagliflozin 200 mg group did not achieve statistical significance in change in daily bolus insulin compared to placebo. Therefore, neither the superiority of sotagliflozin 400 mg versus placebo on mean daily bolus insulin or the rest of the endpoints in the hierarchal order were tested for statistical significance. To complete the review, the results for the remaining secondary endpoints will be shown. These results are for descriptive purposes only and the p-values reported are nominal p-values for study 309."

In both studies 310 and 312, the sotagliflozin groups had a statistically significant change in mean daily bolus insulin at week 24 in favor of sotagliflozin compared to placebo.

Should be revised to read (change bolded and underlined)

"In study 309, the sotagliflozin 200 mg group did not achieve statistical significance in change in daily bolus insulin compared to placebo. Therefore, **no further endpoints in the hierarchal order can be tested for statistical significance for sotagliflozin 200mg group in Study 309. The results for the remaining secondary endpoints for sotagliflozin 200mg group are shown for descriptive purposes only and the p-values reported are nominal p-values for that group in Study 309.**

In both studies 310 and 312, **and sotagliflozin 400mg group in study 309**, the sotagliflozin groups had a statistically significant change in mean daily bolus insulin at week 24 in favor of sotagliflozin compared to placebo."

3) **On page 49, first paragraph, second sentence:**

"Since change in mean daily bolus insulin at week 24 was not statistically significant in study 309, FPG is shown as a descriptive analysis for this study."

Should be revised to read (change bolded and underlined)

"Since change in mean daily bolus insulin at week 24 was not statistically significant for **sotagliflozin 200mg group** in study 309, **fasting plasma glucose** (FPG) is shown as a descriptive analysis for **that dose group**.