U.S. FOOD & DRUG ADMINISTRATION

March 21, 2019

Sidney M. Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Dr. Wolfe,

Thank you for your letter of March 11, 2019 in which you raise concerns regarding new drug application (NDA) 210934 for sotagliflozin, intended as adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus (T1D).

As you are aware, we cannot discuss the details of a pending marketing application or supplemental application based on several Federal statutes and regulations, including the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j), and FDA regulations (21 CFR 20.61(c); 21CFR 312.130(b); 21CFR 314.430(c) and (d)(l). There are limited exceptions to these restrictions on FDA's discussion of a pending application or IND. For example, the Agency may disclose a summary of safety or effectiveness data, if appropriate, at an Advisory Committee meeting (21CFR 314.430(d)(1)); it may disclose certain information when a sponsor provides a written authorization permitting FDA to disclose non-public information about its pending application, and it may disclose information to the extent the sponsor itself has publicly disclosed the information.

As you know and reference in your letter, information related to sotagliflozin was discussed at the January 17, 2019, Endocrinologic and Metabolic Drugs Advisory Committee meeting. We note your comments, notably your concern that data from the phase 3 clinical trials presented in the NDA show an increased risk of diabetic ketoacidosis. We will take your concerns under consideration in our evaluation process.

As always, thank you for sharing your perspective with us.

Sincerely,

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research

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