April 28, 2025

Martin Makary, M.D., M.P.H.
Commissioner of Food and Drugs

Jacqueline Corrigan-Curay, J.D., M.D.
Acting Director, Center for Drug Evaluation and Research

Lisa Yanoff, M.D.
Deputy Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology

John Sharretts, M.D.
Director, Division of Diabetes, Lipid Disorders, and Obesity

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Makary, Corrigan-Curray, Yanoff, and Sharretts,

As organizations dedicated to improving the health and lives of people living with diabetes, we urge you to keep the significant unmet need for adjunctive therapies for individuals with both type 1 diabetes (T1D) and chronic kidney disease (CKD) foremost in your deliberations as you consider regulatory paths forward for sotagliflozin, following its sponsor's receipt of a complete response letter.[1] The magnitude of the daily burden and long-term health complications individuals with T1D face is debilitating, deadly, and wholly unacceptable. People living with T1D are in desperate need of new therapies to help them to achieve glycemic control and to mitigate the risk of heart disease and stroke, kidney damage, vision and limb loss, and early death. We urge you to fully utilize all flexibilities, commensurate with the unmet need, in determining the actions that can be taken to support timely regulatory approval of sotagliflozin for use by individuals living with both T1D and CKD.

As you know, CKD is one of the most serious and common complications of T1D, affecting 30% of Americans with T1D. For people living with both T1D and CKD, difficulties managing either condition can result in a worsening of the other. CKD is known to significantly alter glucose and insulin metabolism, making it more difficult to manage T1D, while at the same time tight glycemic control is essential to slow CKD progression.[2] Notably, kidney failure and initiation of dialysis, as a result of progressed CKD, are known to compound challenges to T1D management and further limit treatment options.[2] As you heard from the more than 100 individuals and organizations who testified at the Open Public Hearing on October 31, 2024 or submitted comments to the docket for the Endocrinologic and Metabolic Disorders Advisory Committee (EMDAC) on sotagliflozin, the needs of people living with T1D and CKD are not being met with existing therapies.

We recognize and appreciate the vital work of the Food and Drug Administration in facilitating innovation in the care and treatment of people with diabetes. On behalf of the millions of individuals with T1D in the United States who stand to benefit from the availability of sotagliflozin as an adjunctive therapy to insulin to improve glycemic control in individuals with T1D and CKD, thank you for your consideration of our views. We look forward to working with you to continue to advance the development of safe and effective therapeutics and to ensure that the patient perspective is at the forefront of regulatory decision making.

Sincerely,

- The diaTribe Foundation
- Breakthrough T1D
- Diabetes Patient Advocacy Coalition
- T1D Exchange
- Taking Control of Your Diabetes
- The Diabetes Leadership Council
- The Diabetes Link

References

1. Lexicon Pharmaceuticals Inc. Lexicon Announces Receipt of Complete Response Letter for Zynquista™ (sotagliflozin). GlobeNewswire News Room. December 20, 2024. Accessed April 23, 2025. https://www.globenewswire.com/news-release/2024/12/20/3000869/0/en/Lexicon-Announces-Receipt-of-Complete-Response-Letter-for-Zynquista-sotagliflozin.html

2. Alicic RZ, Neumiller JJ, Galindo RJ, Tuttle KR. Use of Glucose-Lowering Agents in Diabetes and CKD. *Kidney Int Rep*. 2022;7(12):2589-2607. doi:10.1016/j.ekir.2022.09.018