

October 17, 2024

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No.FDA-2024-N-4422 for “Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 210934 for Sotagliflozin Oral Tablet.”

To Whom it May Concern:

On behalf of The diaTribe Foundation, thank you for the opportunity to provide comments for the Endocrinologic and Metabolic Drugs Advisory Committee’s (Committee) consideration of new drug application 210934 for sotagliflozin oral tablet. As an organization that represents individuals living with diabetes and their advocates, we are pleased to offer our perspective on the value of additional options for disease management for people living with type 1 diabetes, particularly those with co-morbid conditions such as chronic kidney disease (CKD), and the importance of ensuring that innovations in diabetes care and treatment are approved and accessible to all individuals living with diabetes.

More than 38 million Americans like me are impacted by diabetes,¹ a chronic condition that requires proactive daily management of glucose levels to help prevent and reduce the serious and life-threatening complications of the disease. A common comorbidity of type 1 diabetes is CKD, which affects over 20% of Americans with the condition,² with a disproportionate impact on racial and ethnic minority populations.³⁻⁵ CKD can lead to kidney failure and increase the risk of cardiovascular events.²

The diaTribe Foundation maintains a long-standing commitment to engaging in the federal legislative and regulatory processes to help secure policies and programs that improve the lives of individuals living with diabetes. To that end, the voices of people with diabetes must be heard when discussing treatments that directly affect them, and we appreciate the Food and Drug Administration (FDA) and the Committee providing this opportunity.

The diaTribe Foundation

The mission of The diaTribe Foundation is to help people with diabetes and prediabetes and to advocate for action. Our goal is to ensure that people have the resources and education needed to thrive with diabetes. The diaTribe Foundation is dedicated to bringing people with diabetes to the conversation on regulatory issues, connecting the field and the diabetes community, and changing the narrative around diabetes. Through our publication, *Learn*, which reaches more than six million people each year, we offer deep insights into the patient experience and closely cover the latest research, treatments, and initiatives in diabetes.

The diaTribe Foundation Comments
Docket No.FDA-2024-N-4422
Endocrinologic and Metabolic Drugs Advisory Committee Meeting

In addition, because everyone with diabetes deserves to have the tools, therapies, and technologies to live their best life, we established *The Time in Range Coalition* (TIRC), a multi-stakeholder group of foundations, non-profit organizations, researchers, people with diabetes, clinicians, and industry with the goal of establishing time in range (TIR) as an essential part of diabetes care and making TIR accessible to all people with diabetes and their care teams. Using TIR in daily diabetes management can positively change lives^{6,7}—we are spearheading the work to make that a reality for everyone with diabetes.

The diaTribe Foundation also aims to reduce the impact of diabetes on society and improve the lives of people with diabetes by fostering an understanding of the disease and eliminating misplaced blame through the work of our program, *dStigmatize*.

Value of Additional Therapeutic Options

As a person living with diabetes for over a quarter of a century, the innovations I have been able to incorporate into my own diabetes management have dramatically improved my quality of life. Some of those innovations have been therapeutic and others have included technology. The options that have made the most significant impact for me have included insulin, automated insulin delivery (AID) systems, and adjunctive therapies. These newer non-insulin medications have been game changers for millions of people living with type 2 diabetes. Type 1 and type 2 diabetes share the risk of the same associated complications, with the development and progression of conditions like CKD occurring through very similar mechanisms⁸—still, people with type 1 diabetes do not have access to the medicines that doctors have been using to address these same issues in type 2 diabetes management.

While diabetes care has evolved rapidly in recent years, disease management remains a significant challenge for millions of Americans unable to achieve glycemic levels that mitigate risks for diabetes related complications. Despite my 26 years living with diabetes and professional role as a diabetes advocate, I will be the first one to share that managing glucose levels remains a very real, very frustrating struggle. Despite a very intentional nutrition plan, daily exercise, significant education and access to insulin pumps and continuous glucose monitors (CGMs), life with diabetes is unpredictable. As I get older, the effects of the natural aging process combined with diabetes have resulted in significant insulin resistance and hormonal changes that impact my glucose levels and increase my risk of developing diabetes related complications.

I am not alone—many individuals are unable to manage their blood sugars in a healthy glucose range solely with insulin. In fact, less than 30% of people with type 1 diabetes currently have an A1C at the target of less than 7%.⁸ With insulin and AID, I struggled to get my A1c below 7% until my endocrinologist prescribed an adjunctive therapy to my intensive insulin therapy. Using this medication has reduced my insulin resistance, lowered my A1c consistently below 7%, decreased my appetite and flattened out my glucose levels. Despite the improvements to my health and quality of life, because they are not approved for type 1 diabetes management,

The diaTribe Foundation Comments
Docket No.FDA-2024-N-4422
Endocrinologic and Metabolic Drugs Advisory Committee Meeting

access to these medications has been cost prohibitive and oftentimes impossible for me and others with type 1 diabetes to obtain. Numerous times over the past four years I have contemplated how I will spend the rest of my life fighting my body and fighting for the tools I need to continue fighting this disease. Continued innovation in safe and effective therapeutic options is critical to allowing patients and their care providers to personalize their treatment to meet their individual needs.

Benefits of Improved Disease Management

Managing type 1 diabetes alongside at least one other chronic condition is incredibly common—27% of individuals with type 1 diabetes have at least one co-occurring autoimmune disease,¹⁰ while 33% of adolescents and young adults with type 1 in the U.S. have at least one related complication or comorbidity.¹¹ For people living with both type 1 diabetes and CKD, difficulties managing either condition can set off a sort of vicious cycle. CKD is known to significantly alter glucose and insulin metabolism,^{12,13} making it more difficult to manage type 1 diabetes, while at the same time tight glycemic control is essential to slow CKD progression.^{14,15} Notably, kidney failure and initiation of dialysis as a result of progressed CKD is known to add additional challenges to type 1 diabetes management and further limit treatment options.¹³

While these dynamics have been understood for 30 years, treatment options indicated for individuals with type 1 diabetes and CKD have remained largely stagnant over that same time.^{8,14} A therapy now exists and has been shown to provide tremendous benefits, yet people with type 1 diabetes and CKD still don't have approval and access to it.^{8,14} Use of the adjunctive therapy sotagliflozin in type 1 diabetes has been found to increase glucose stability, reduce HbA1c and reduce insulin needs, in addition to improving body weight and blood pressure.^{16,17} This symptom improvement can also have a positive impact on quality of life, improving treatment satisfaction and reducing diabetes distress.¹⁸

Upon diagnosis, each person with type 1 diabetes quickly learns about the life-saving properties of insulin as well as the risks involved in taking it. We spend the rest of our lives managing those benefits and inherent risks—24 hours a day, 7 days a week, 365 days a year. While adjunctive therapies may introduce new variables to manage, this is a subset of people who are uniquely poised and eager to navigate the risks that come with the development of new treatments that have been proven to reduce hyperglycemic events, increase blood glucose stability, lower HbA1C levels, reduce insulin needs and have a positive impact on quality of life and daily functioning.^{16,18} As for the community members who are managing type 1 diabetes and CKD, they are acutely aware of the risks that the advancement of diabetes comorbidities pose. There is an essential need for treatment options to exist and be available for those individuals and their healthcare teams to determine the best options for personalized care.

The diaTribe Foundation Comments
Docket No.FDA-2024-N-4422
Endocrinologic and Metabolic Drugs Advisory Committee Meeting

Today, as a diabetes advocate, I see how unique diabetes looks for members of the community and how different treatment options are needed to effectively meet the needs of individuals living with this disease. As the Committee and FDA consider this application, we look forward to full consideration of ways to ensure that the benefits outweigh the risks for individuals with type 1 and CKD, including with regard to mitigating the risk of diabetic ketoacidosis (DKA). Many patient advocacy groups work to educate and encourage the importance of recognizing the familiar signs of DKA and leveraging ketone monitoring as a way to prevent it. Additionally, we also urge continued efforts toward the development of a combined ketone and continuous glucose monitor, which, when accessible, could help in reducing DKA.

The diaTribe Foundation is committed to ensuring that people with diabetes have access to the therapies, tools and information that they need to live their best and healthiest lives, and hope that the approval of sotagliflozin will give people with type 1 diabetes and CKD a valuable new treatment option.

Thank you again for the opportunity to provide comment to the Committee. We respectfully request that you consider these perspectives as you conduct your review.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Heverly". The signature is fluid and cursive, with a large, stylized initial "J".

Julie Heverly
Senior Director, Time in Range Coalition
The diaTribe Foundation

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The diaTribe Foundation Comments
Docket No.FDA-2024-N-4422
Endocrinologic and Metabolic Drugs Advisory Committee Meeting

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