



May 27, 2021

Center for Devices and Radiological Health
Food and Drug Administration
Bldg. 66, Room 1116
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Docket Number FDA-2021-N-0270

Beyond Type 1 is a nonprofit organization changing what it means to live with diabetes. Through platforms, programs, resources, and grants, Beyond Type 1 is uniting the global diabetes community and providing solutions to improve lives today. Founded in 2015 with a focus on education, advocacy, and the path to a cure for Type 1 diabetes, Beyond Type 1 has grown to also include programs for those with Type 2 diabetes.

We are pleased to submit comments on behalf of Beyond Type 1 in support of the Biologics License Application (BLA) for Teplizumab (PRV-031) for the delay of clinical Type 1 diabetes for those who are deemed to be at-risk.

For over 1.6 million Americans with Type 1 diabetes (T1D), the clinical treatment is exogenous insulin, which is not a cure for this autoimmune disease that permanently destroys beta cells. Determining the correct dosage is based on constantly changing factors, including food, stress, activity level, and hormones. The never-ending exercises of attempting to prevent both acute and long-term complications through daily management can be mentally, emotionally, and financially devastating for both those with diabetes and their families. Despite intensive monitoring and adjustments, T1D has been shown to decrease life expectancy, with reductions increasing for those diagnosed under the age of 10.¹

Since the discovery of insulin 100 years ago, we have learned that those at-risk for developing Type 1 diabetes have diabetes-related antibodies which can be detected through a blood test.

¹[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)31506-X/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31506-X/fulltext)



For individuals with 2 or more antibodies, an official diagnosis is almost guaranteed.² First-degree family members of those already diagnosed with T1D have a 15x lifetime risk of developing this chronic disease in their lifetime.³

The diagnosis of Type 1 diabetes is life-altering, as is the possibility of delayed onset of this disease through a single 14-day infusion treatment. The prevention of a T1D clinical diagnosis by up to two years or more — made possible by Teplizumab, according to clinical trial data published in 2019⁴ — gives the individual and loved ones the gift of time to:

- Learn more about the disease and its management, arming them with the knowledge they will need to navigate the future with T1D
- Live a life for a few more years without insulin injections, invasive needles, counting carbohydrates, sleep deprivation, fear of hypo- and hyperglycemia, and the psychological distress that impacts families when an individual has a chronic illness
- Prevent diabetic ketoacidosis (DKA) — a traumatic, life-threatening condition present in roughly 46% of new T1D diagnoses⁵ that can lead to coma or death and is a predictor of poor long-term glycemic control⁶

With the largest digital footprint of any diabetes organization in the world, Beyond Type 1 has witnessed firsthand what a potential delay in diabetes diagnoses means to those affected by Type 1 diabetes. The reaction to news coverage of Teplizumab trial data presented in 2019 and 2020 was overwhelmingly positive and hopeful, with many inquiring as to when this treatment would be available for their family. One community member on Facebook weighed in to say that “With children especially, every day, week, month we can give them without the daily need to handle this disease is more time to be more carefree ... get more mature and be able to handle the self-care a little bit more easily;” this comment is representative of the general community sentiment we’ve observed related to Teplizumab.

² https://diabetes.diabetesjournals.org/content/54/suppl_2/S52

³ <https://www.diabetes.org/diabetes/genetics-diabetes>

⁴ Herold, et al. “An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes” *N Engl J Med* 2019; 381:603-613 DOI: 10.1056/NEJMoa1902226

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8029525/>

⁶ <https://care.diabetesjournals.org/content/40/9/1249>



The potential approval of Teplizumab offers a ray of hope for those at-risk of developing T1D, and its approval offers a meaningful step forward both in addressing the dangers of unpredictable onset and in allowing families to avoid the burdens of this disease while planning for the future.

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