FDA Approves Teplizumab To Delay Onset of Type 1 Diabetes

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US Food and Drug Administration (FDA) approved the use of Teplizumab under the brand name Tzield, an immunotherapy drug, which has been shown to significantly delay the onset of type 1 diabetes. This is the first potential disease modifying therapy for patients with type 1 diabetes in the United States, for whom there is currently no approved treatment other than a lifetime of subcutaneous insulin injections.

Founding Director and Professor Emeritus **Jeff Bluestone, PhD**, currently CEO and President of Sonoma Biotherapeutics, was instrumental in developing the drug. Dr. Bluestone and his colleagues labored against the odds to bring the therapy to patients at risk for this devastating disease.

In addition, our TrialNet team including **Stephen Gitelman, MD**, the Mary B. Olney, MD / KAK Distinguished Professor in Pediatric Diabetes and Clinical Research, and Director **Mark Anderson, MD, PhD**, played a crucial role in the nationwide clinical trials that spanned two decades, the findings from which ultimately led to this FDA approval. In the pivotal trial that led to this approval, a single 14-day dose of Teplizumab was shown to delay the onset of type 1 diabetes in children and adults by an average of at least two years in pre-symptomatic patients.

As the first approved immunotherapy drug for diabetes, this new treatment will make a huge difference in the lives of at-risk individuals. Diabetes Center congratulates Drs. Bluestone, Gitelman, and Anderson, and all the researchers and clinicians across the country, especially **Kevan Herold MD**, C.N.H. Long Professor of Immunobiology and of Medicine at Yale School of Medicine, who worked tirelessly to bring this drug to those who need it most. Thank you to the patients and families that participated in the clinical trials, which are fueled by a combination of philanthropic gifts, grants, and NIH funding.

Our deep appreciation also to all of you for supporting this innovative therapy from laboratory research to a breakthrough treatment.

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