FDA Approves Drug for Pediatric Stage 3 Type 1 Diabetes

var addthis_share = { templates: { twitter: "The U.S. Food and Drug Administration has approved Tzield (teplizumab) injection to delay the loss of the body’s own insulin production for pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 Type 1 Diabetes. "We welcome this accelerated approval by the FDA, which recognizes the potential of Tzield to delay the progression of recently diagnosed stage 3 T1D in children aged eight to 17 years," said the Head of Development at Sanofi, which acquired Teplizumab from Provention Bio in 2023. Supporting Data" } }

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Supporting Data

A large clinical trial called the PROTECT Study looked at whether teplizumab could slow down the loss of the body's own insulin production in children and teenagers recently diagnosed with Stage 3 T1D. The study was a randomized, double-blind, placebo-controlled trial. This means patients were randomly assigned to receive either teplizumab or a placebo (an inactive treatment), and neither the patients nor the research team knew which treatment each patient was receiving. Patients received their assigned treatment once daily through an IV for 12 days, followed by another 12-day course of treatment (drug or placebo) six months later.

The study included 328 patients between the ages of 8 and 17 who had been diagnosed with Stage 3 T1D within the past six weeks. All patients in the study still had some insulin-producing cells (called beta cells) that were working at the time they enrolled.

The study measured how well the beta cells were still working at 78 weeks (about 18 months) by testing levels of a protein called C-peptide in the blood. C-peptide is a reliable indicator of how much insulin the body is still producing on its own. At 78 weeks, patients who received teplizumab showed a significantly smaller decline in beta cell function compared to patients who received the placebo. This means teplizumab helped slow down the loss of the body's own insulin production.

Leadership Reflects

"As everyone in this field knows, it's been a long road to here," said **Jeff Bluestone PhD**, instrumental in the drug's development, recalling trusted colleagues who collaborated along the way. "Congrats to all that made this possible: Kevan Herold; Lucienne Chatenoud; Bob Zivin and Linda Jolliffe at Ortho; Scott Koenig and others at Macrogenics; Francisco Leon and Leni Ramos at Provention; Sanofi and many others."

The inspiring news marks a clear path to the future. "The FDA approval marks a historic shift in how we can approach type 1 diabetes. For more than a century our approach has been reactive—replacing insulin as a result of the autoimmune destruction of the pancreatic islets," said center director **Mark Anderson MD PhD**. "This new approach allows us to slow the autoimmune process resulting in better control and a path to even more targeted treatments of the immune attack of the islets.

Looking forward

University of California San Francisco is anchored in a deeply integrated ecosystem where world-class basic science, formal institutional training, and a robust culture of "team science" thrives together as curiosity-driven exploration turns complex biological mysteries into the medical realities of tomorrow. Diabetes Center is proud to be part of this journey.

This article was in notable part adapted from FDA's press release.

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