Press Release

Sanofi's Tzield accepted for priority review in the US for young children with stage 2 type 1 diabetes

- If approved, Tzield would be the first disease-modifying therapy to delay the onset of stage 3 T1D in children aged one and older diagnosed with stage 2 T1D
- Tzield slows disease progression by protecting the insulin-secreting beta cells of the pancreas
- The priority review is based on interim results from the PETITE-T1D phase 4 study

Paris, January 5, 2026. The US Food and Drug Administration (FDA) has accepted for priority review the supplemental biologic license application (sBLA) for Tzield (teplizumab-mzwv) to expand the current age indication from eight years and above, to as young as one year old and above to delay the onset of stage 3 type 1 diabetes (T1D) in patients diagnosed with stage 2 T1D. The sBLA is supported by the positive interim one-year data from the ongoing PETITE-T1D phase 4 study (clinical study identifier: NCT05757713), evaluating the safety and pharmacokinetics of Tzield in young children. The target action date for the FDA decision is April 29, 2026.

"This priority review emphasizes the urgent need for innovative therapies like Tzield which has the potential to prevent the natural progression of T1D by delaying the loss of endogenous insulin production. This might be particularly significant in this young population, as it is well documented that the autoimmune attack that drives this disease in many cases, begins, early in life," said ***Christopher Corsico,*** *Global Head of Development at Sanofi. "If approved, Tzield could represent an important advance for delaying the onset of stage 3 type 1 diabetes in early childhood, which would benefit patients and caregivers alike."*

Interim data for the PETITE-T1D phase 4 study was presented at the 51st Annual Conference of the International Society for Pediatric and Adolescent Diabetes and simultaneously published in *Diabetologia.*

Priority review is given to regulatory applications seeking approval for therapies that have the potential to provide significant improvements in the treatment, diagnosis, or prevention of serious conditions.

The safety and efficacy of Tzield in the PETITE-T1D population has not been approved by any regulatory authority.

About PETITE-T1D

PETITE-T1D (clinical study identifier: NCT05757713) is an ongoing phase 4 single-arm, non-randomized, open-label, multicentre study designed to assess the safety and pharmacokinetics of Tzield in children under eight years diagnosed with stage 2 T1D. Stage 2 T1D is defined by the presence of two or more T1D-related autoantibodies and dysglycaemia.

The study has enrolled 23 participants. The regimen consists of an intravenous infusion of Tzield once daily for 14 consecutive days. The study duration for each individual may last up to 26 months for follow up and monitoring.

About Tzield

Tzield (teplizumab-mzwv) is a CD3-directed monoclonal antibody. Tzield is the first and only disease-modifying therapy in autoimmune T1D; it was first approved in the US in November 2022 to delay the onset of stage 3 T1D in adults and children eight years and older diagnosed with stage 2 T1D. Today, it is also approved in China, the UK, Canada, Israel, the Kingdom of Saudi Arabia, the United Arab Emirates, and Kuwait for the same indication. In November 2025, the European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive recommendation for the same population (Tzield will be known as Teizeild in the EU). Other regulatory reviews are ongoing.

About autoimmune T1D

T1D is a progressive autoimmune disease where the body's ability to regulate blood sugar levels is impacted due to the gradual destruction of insulin-producing beta cells by one's own immune system. There are four stages to the progression of T1D:

- In stage 1, the autoimmune attack to the beta cells has started, and this can be detected by the presence of 2 or more T1D-related autoantibodies in the blood. During stage 1, blood sugar levels are in a normal range (normoglycaemia). At this stage, T1D is presymptomatic.
- In stage 2 (also presymptomatic), in addition to the presence of 2 or more T1D-related autoantibodies, blood sugar levels are now abnormal (dysglycaemia) due to the progressive loss of beta cells/beta-cell function.
- Stage 3 (also known as clinical stage) comes once a significant portion of the beta cells have been destroyed. At this point, rising blood sugar levels reach the point of clinical hyperglycaemia (which defines diabetes), and many people will start to experience the classic symptoms that come with the onset of stage 3 T1D: increased thirst, frequent urination, unexplained weight loss, blurred vision, and generalized fatigue. Management of stage 3 T1D requires daily and burdensome insulin replacement therapy.
- Stage 4 is defined as long-standing autoimmune T1D, often accompanied by evidence of chronic diabetic complications, where little to no beta cells remain (it's been estimated that the beta-cell mass is reduced by up to 95%). At this point, the T1D-related autoantibodies might not be present anymore in the blood, as most beta cells have been rendered useless by the autoimmune attack.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and creating compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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