Press Release

Sanofi's Tzield approved in the US to delay the onset of stage 3 type 1 diabetes in young children

- Expanded approval includes children aged one year and above with stage 2 T1D to delay the onset of stage 3
- Tzield is the first disease-modifying therapy for children aged one year and above diagnosed with stage 2 T1D

Paris, April 22, 2026. The US Food and Drug Administration (FDA) has approved the supplemental biologic license application for Tzield (teplizumab-mzwv), expanding the indication from eight years and older to as young as one year of age to delay the onset of stage 3 type 1 diabetes (T1D) in patients diagnosed with stage 2 T1D. The approval was granted under a priority review process and is supported by one-year data from the PETITE-T1D phase 4 study (clinical study identifier: NCT05757713), evaluating safety and pharmacokinetics in young children.

> *"This approval opens an important new chapter in diabetes care for young children with stage 2 type 1 diabetes and their families," said* **Kimber Simmons**, MD, MS, Associate Professor of Pediatrics at the Barbara Davis Center, Aurora, Colorado, US. *"This is especially important because these children are often at the highest risk of progressing quickly and without warning. Delaying the onset of stage 3 type 1 diabetes during the years when management is often most difficult because of a child's small size and dependence on caregivers could have a truly meaningful impact for families."*
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> *"The autoimmune attack driving this disease often begins early in life, and the burden that autoimmune T1D poses in this very young population and their families is significant,"* said **Christopher Corsico,** Global Head of Development at Sanofi. *"This approval underscores the importance of targeting the immune system early in autoimmune type 1 diabetes, aiming to impact its natural progression by delaying the loss of insulin production in the pancreas."*

Tzield is also being reviewed by the FDA for a potential indication to delay the progression of stage 3 T1D in patients eight years of age and older recently diagnosed with stage 3 T1D.

Tzield is approved in the EU (under the name Teizeild), in the UK, China, Canada, Israel, Saudi Arabia, the UAE, Kuwait, and Brazil to delay the onset of stage 3 T1D in adults and pediatric patients eight years and older diagnosed with stage 2 T1D. Other regulatory reviews are ongoing. Tzield was previously granted FDA breakthrough therapy designation and orphan drug designation, for medicines that treat rare diseases affecting fewer than 200,000 people in the US.

About PETITE-T1D

PETITE-T1D (clinical study identifier: NCT05757713) is a phase 4 single-arm, non-randomized, open-label, multi-center 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 abnormal blood sugar levels (dysglycemia).

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 including screening for eligibility, treatment administration and follow-up.

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 two or more T1D-related autoantibodies in the blood. During stage 1, blood sugar levels are in a normal range (normoglycemia). At this stage, T1D is presymptomatic.
- In stage 2 (also presymptomatic), in addition to the presence of two or more T1D-related autoantibodies, blood sugar levels become abnormal (dysglycemia) 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 hyperglycemia (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-cell function remains (it has been estimated that 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 Tzield

Tzield (teplizumab-mzwv) is a CD3-directed monoclonal antibody. Tzield is the first disease modifying medicine 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. Tzield is also approved in the EU (under the name Teizeild), the UK, China, Canada, Israel, Saudi Arabia, the UAE, Kuwait, and Brazil to delay the onset of stage 3 T1D in adults and children eight years and older diagnosed with stage 2 T1D.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering 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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