Press Release

Sanofi's Tzield approved in the US as the first disease-modifying therapy for patients recently diagnosed with stage 3 type 1 diabetes

- Accelerated approval in children aged eight to 17 years old recently diagnosed with stage 3 T1D to delay the decline in endogenous insulin production
- Approval based on the PROTECT phase 3 study and additional data from the global clinical development program from over 900 patients who received Tzield

Paris, June 13, 2026. The US Food and Drug Administration (FDA) has granted accelerated approval to Tzield (teplizumab-mzwv) to delay the decline in endogenous (own) insulin production in children aged eight to 17 years recently diagnosed with stage 3 T1D. Tzield is not effective as a disease-modifying therapy in non-autoimmune dysglycemic conditions.

> *"We now have a novel therapy that targets the autoimmune and progressive nature of stage 3 type 1 diabetes,"* said **Aaron J. Kowalski**, PhD, CEO of Breakthrough T1D. *"Approximately 64,000 people are diagnosed with T1D every year. We are excited that the approval of Tzield in this indication provides a treatment option for certain patients diagnosed in stage 3 T1D, which is when many start experiencing common symptoms of the disease."*

The approval was supported by data from the PROTECT phase 3 study (clinical study identifier: NCT03875729), evaluating beta cell function as assessed by significantly slowing the decrease in mean C-peptide levels (area under the curve after a four-hour, mixed-meal tolerance test; difference in least-squares means 0.13 pmol/mL; 95% confidence interval: 0.09-0.17; $p<0.001$) at trial completion, compared to placebo, as well as data from the broader clinical development program that included over 900 patients who received Tzield. Adverse events observed in the PROTECT phase 3 study were consistent with previous studies.

The most common adverse reactions were lymphopenia, vomiting, rash, leukopenia, diarrhea, neutropenia, increased liver transaminase, and headache. Serious events such as cytokine release syndrome and life-threatening cases of viral reactivation have been reported with Tzield. Patients who are immunocompromised are at increased risk for viral reactivation.

This indication is granted under accelerated approval based on evidence of reduced C-peptide decline. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory study(ies).

Medicines that receive accelerated approval are intended to treat serious conditions that fill an unmet medical need, based on a surrogate endpoint reasonably likely to predict clinical benefit. In line with this, the confirmatory BETA-PRESERVE phase 3 study (clinical study identifier: NCT07088068) was initiated and is currently enrolling participants.

> *"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 **Christopher Corsico**, Global Head of Development, Sanofi. *"Tzield will now offer a new pathway in the treatment paradigm of stage 3 T1D, one that we hope will further enable healthcare providers in the US to take a more proactive approach to disrupt the underlying autoimmune attack against insulin-producing beta cells."*

Prior to this approval in recently diagnosed stage 3 T1D, in April 2026, the FDA expanded the indication to delay the onset of stage 3 T1D in adults and children eight years and older with stage 2 T1D, to include children aged one year and above. It is also approved to delay the onset of stage 3 T1D in adults and children eight years and older with stage 2 T1D in the UK, the EU (under the name Teizeild), China, Australia, Canada, Israel, Saudi Arabia, the UAE, Kuwait, Brazil and Switzerland. Regulatory reviews are ongoing in other jurisdictions around the world. Tzield was previously designated by the FDA as breakthrough therapy and was granted orphan drug designation, for investigational medicines that treat rare diseases affecting fewer than 200,000 people in the US.

About PROTECT

PROTECT was a phase 3, randomized, double blind, placebo-controlled, multinational study. It enrolled 328 children and adolescents (Tzield n=217, placebo n=111) aged eight to 17 years diagnosed with clinical stage 3 T1D in the preceding six weeks; randomization ratio of Tzield to placebo was 2:1. Participants received a first course of 12 daily infusions (of either Tzield or placebo) at randomization, followed by a second course of 12 daily infusions after 26 weeks (approximately six months). All participants received standard-of-care medicines as required.

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 (normoglycemia). 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 (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's 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) is a CD3-directed monoclonal antibody. Tzield is the first disease-modifying therapy in autoimmune T1D; it was 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. In April 2026, the FDA expanded this indication to include children aged one year and above. Today, it is also approved in to delay the onset of stage 3 T1D in adults and children eight years and older with stage 2 in the UK, the EU (under the name Teizeild), China, Australia, Canada, Israel, Saudi Arabia, the UAE, Kuwait, Brazil and Switzerland. Other regulatory reviews are ongoing.

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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