Press Release

Sanofi's Tzield accepted for expedited review in the US for stage 3 type 1 diabetes through FDA Commissioner's National Priority Voucher pilot program

- If approved, Tzield would be the first disease-modifying therapy to delay the progression of stage 3 T1D in adults and pediatric patients eight years of age and older recently diagnosed with stage 3 T1D
- Tzield is also being reviewed under the accelerated approval program

Paris, October 20, 2025. The US Food and Drug Administration (FDA) has accepted for expedited review the supplemental biologics license application (sBLA) for Tzield (teplizumab-mzwv) to delay the progression of stage 3 type 1 diabetes (T1D) in adults and pediatric patients eight years of age and older recently diagnosed with stage 3 T1D. The FDA nominated Tzield for the Commissioner's National Priority Voucher (CNPV) pilot program based on its potential to address a large unmet medical need. The CNPV program aims to shorten the review process from what normally takes 10-12 months to 1-2 months, while maintaining FDA's rigorous safety and efficacy standards.

> *"We welcome that Tzield has been accepted for expedited review by the FDA under the Commissioner's National Priority Voucher pilot program, potentially enabling us to go further and faster for patients and lead the way with breakthrough science," said* **Olivier Charmeil**, Executive Vice President, General Medicines, Sanofi*. "This is a recognition of the breakthrough innovative profile of Tzield, its ability to potentially prevent the natural progression of T1D, and the significant unmet medical need that remains in this area which has seen limited treatment advances in the last 100 years."*

The sBLA is supported by the results from the PROTECT phase 3 study, which met its primary endpoint, evaluating preservation of beta cell function as assessed by significantly slowing the decrease in mean C-peptide levels (area under the curve [AUC] after a four-hour mixed meal tolerance test) at trial study completion, compared to placebo. Additionally, the sBLA builds on the clinical development program of Tzield including approximately~1,000 patients.

Adverse events observed in the PROTECT phase 3 study were consistent with previous studies. Most common adverse events were headache, nausea, rash, lymphopenia, leukopenia and gastrointestinal symptoms, consistent with the mode of action of cytokine release. 1.8% of those who received Tzield in the PROTECT study developed cytokine release syndrome possibly or probably related to Tzield.

Additionally, Tzield is being reviewed under the accelerated approval program, a pathway that allows the FDA to review therapies 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 requirement, the confirmatory BETA-PRESERVE phase 3 study (clinical study identifier: NCT07088068) was initiated recently and is currently enrolling participants.

Tzield is approved in the US, the UK, China, Canada, Israel, the Kingdom of Saudi Arabia, the United Arab Emirates, and Kuwait to delay the onset of stage 3 T1D in adults and pediatric patients eight years and older diagnosed with stage 2 T1D. Regulatory reviews are ongoing in

the EU and 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.

The safety and efficacy of Tzield in stage 3 T1D have not yet been approved by any regulatory authority.

About PROTECT

PROTECT (clinical study identifier: NCT03875729) was a phase 3, randomized, double blind, placebo-controlled, multi-national study. It enrolled 328 children and adolescents (Tzield n=217, placebo n=111) aged eight-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 (approx. six months). All participants received standard-of-care medicines as required.

The primary objective of PROTECT was to determine whether Tzield could preserve beta cell function measured by C-peptide, compared to placebo. This was assessed via the trial's primary endpoint, which measured the difference in mean change of C-peptide level (area under the time-concentration curve [AUC] measured after a four-hour mixed meal tolerance test) from baseline to Week 78 between both groups.

Key secondary endpoints included change in HbA1c, time in range as measured with a CGM, clinically important low blood sugar (hypoglycemia) events and exogenous insulin use. Time in range was defined as: ≥ 70 but ≤180 mg/dL. Clinically relevant hypoglycemic events were defined: level 2 hypoglycemia (<54 mg/dL / 3.0 mmol/L) and level 3 hypoglycemia as episodes of severe cognitive impairment requiring external assistance for recovery, even in the absence of a blood glucose reading.

Other secondary endpoints were adverse events and overall safety aspects, as well as pharmacokinetics and immunogenicity of Tzield. An observational extension study following participants for a further 42 months is ongoing.

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 approved in the US in November 2022 to delay the onset of Stage 3 type 1 diabetes in adults and children eight years and older diagnosed with stage 2 T1D. Today, it is also approved in the UK, China, Canada, Israel, the Kingdom of Saudi Arabia, the United Arab Emirates, and Kuwait for the same indication. Regulatory reviews are ongoing in the EU and other jurisdictions around the world.

About autoimmune T1D

T1D is a progressive autoimmune condition 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 remain (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 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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