Press Release

Sanofi's Teizeild approved in the EU for patients with stage 2 type 1 diabetes

- Approval based on the TN-10 phase 2 study that demonstrated a significant delay of onset of stage 3 T1D in stage 2 T1D patients
- Teizeild represents a potential significant change in the treatment of autoimmune T1D, preventing the natural disease progression protecting beta-cell function

Paris, January 12, 2026. The European Commission has approved Teizeild (teplizumab) to delay the onset of stage 3 type 1 diabetes (T1D) in adult and pediatric patients eight years of age and older with stage 2 T1D. This follows the positive opinion by the European Medicines Agency's Committee for Medicinal Products for Human Use. Teizeild is the first T1D disease-modifying therapy approved in the EU, marking a significant milestone in the treatment of this progressive autoimmune disease. The approval is based on positive results from the TN-10 phase 2 study (clinical study identifier: NCT01030861) demonstrating that Teizeild delayed the onset of stage 3 T1D by a median of two years compared to placebo, in adults and children aged eight years and older with stage 2 T1D.

> *"We are pleased that, for the first time, we will be able to offer patients and families in the EU a disease-modifying therapy designed to address the underlying immune process of type 1 diabetes,"* said **Olivier Charmeil,** Executive Vice President, General Medicines, Sanofi. *"We remain committed to working with external stakeholders across the EU to bring patients the benefits of Teizeild, a unique therapy that may prevent the natural progression of type 1 diabetes by protecting beta-cell function."*

At the end of the TN-10 phase 2 study, the proportion of patients who remained in stage 2 T1D was almost twice as high in the Teizeild group as in the placebo group (57% vs 28%). The safety profile was consistent with the one observed in previous studies of Teizeild. The most frequently observed adverse events were blood or bone marrow-related (transient lymphopenia) in 75% of the participants and dermatologic or skin-related (rash) in 36% of the participants.

Teizeild (known as Tzield outside the EU) is also 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 children aged eight years and older with stage 2 T1D. As previously communicated, following the positive CHMP recommendation for this newly approved indication, Sanofi has decided not to progress with a second application for Teizeild in recently diagnosed stage 3 T1D at this time. Next steps are under evaluation. Other regulatory reviews are ongoing.

About TN-10

The pivotal TN-10 phase 2 study was a randomized, placebo-controlled, double-blind study which evaluated Teizeild for the delay of stage 3 T1D in adults and children aged eight years and older diagnosed with stage 2 T1D (presence of at least two T1D-related autoantibodies and dysglycemia) who are relatives of people living with autoimmune T1D. Seventy-six participants aged eight to 45 were enrolled (Teizeild n=44, placebo n=32). They were randomized to receive a single 14-day course of either Teizeild or placebo.

The primary endpoint was the elapsed time from randomization to the clinical diagnosis of autoimmune stage 3 T1D (progression from stage 2 T1D to stage 3 T1D). Key secondary end points included safety and tolerability.

Results demonstrated that the median time to the diagnosis of stage 3 T1D was 48.4 months in the Teizeild group and 24.4 months in the placebo group. The disease was diagnosed in 19 (43%) of the participants who received Teizeild and in 23 (72%) of those who received placebo. The

hazard ratio for the diagnosis of type 1 diabetes (Teizeild vs. placebo) was 0.41 (95% CI: 0.22 to 0.78; p=0.006 by adjusted Cox proportional-hazards model). There were expected adverse events of rash and transient lymphopenia.

About Teizeild

Teizeild (teplizumab) is a CD3-directed monoclonal antibody. Teizeild 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. 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 (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 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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Sanofi forward-looking statements

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