Press Release

Sanofi's Teizeild recommended for EU approval by the CHMP for patients with stage 2 type 1 diabetes

- Recommendation based on the TN-10 study, demonstrating Teizeild's ability to delay the onset of stage 3 type 1 diabetes (T1D), compared to placebo, in adults and children with stage 2 T1D
- If approved, Teizeild would become the first disease-modifying T1D therapy in the EU

Paris, November 14, 2025. The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Teizeild (teplizumab) to delay the onset of stage 3 T1D in adult and pediatric patients eight years of age and older with stage 2 T1D.

The positive opinion is supported by positive data from the TN-10 phase 2 study (clinical study identifier: NCT01030861), which demonstrated that Teizeild significantly delayed the onset of stage 3 T1D by a median of approximately two years compared to placebo. At the end of the study, the proportion of patients who remained in stage 2 T1D was twice as high in the Teizeild group as in the placebo group (57% vs 28%). The safety profile was consistent with previous studies of Teizeild, with the most frequently observed adverse events being blood or bone marrow-related (transient lymphopenia) and dermatologic or skin-related (rash).

> *"We are encouraged by the positive opinion in stage 2 T1D, which represents an important step toward transforming the 100-year-old treatment paradigm for autoimmune T1D,"* said **Olivier Charmeil**, Executive Vice President, General Medicines at Sanofi*. "By targeting the disease at an early stage, Teizeild can help prevent the natural progression of T1D, extending the time patients can stay independent of insulin."*

Teizeild (known as Tzield outside the EU) is a CD3 directed monoclonal antibody. It 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 children aged eight years and older with stage 2 T1D. Following the positive CHMP recommendation and based on conversations with the EMA, at this time Sanofi will not progress its application for recently diagnosed stage 3 T1D and is evaluating next steps. Additional regulatory reviews are ongoing in 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 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 TN-10

TN-10 was a pivotal phase 2, randomized, placebo-controlled, double-blind study. The study evaluated Teizeild for the prevention or delay of stage 3 T1D in people diagnosed with stage 2 T1D (presence of at least two T1D-related autoantibodies and dysglycemia) who were 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.

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 statement

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