Press Release

Tzield approved in China as first disease-modifying therapy for adult and pediatric patients with stage 2 type 1 diabetes

- Approval based on the TN-10 study, demonstrating Tzield's ability to delay the onset of stage 3 T1D in adult and pediatric patients aged eight years and older, with stage 2 T1D compared to placebo
- Additional regulatory reviews are ongoing across different disease stages by regulatory authorities around the world

Paris, September 10, 2025- The Chinese National Medical Products Administration (NMPA) has approved Tzield (teplizumab) as the first disease-modifying therapy in autoimmune type 1 diabetes (T1D) indicated to delay the onset of stage 3 T1D in adult and pediatric patients aged eight years and older with stage 2 T1D. The review was completed under priority review, following the recognition by NMPA of Tzield's innovative profile and the benefit it brings to pediatric patients.

The approval is based on the positive results from the TN-10 phase 2 study, which demonstrated Tzield's ability to delay the onset of stage 3 T1D, compared to placebo. The pivotal study demonstrated that a once-daily, single and consecutive 14-day course of Tzield delayed the median onset of stage 3 T1D by 48.4 months vs 24.4 months observed in the placebo group.

> *"This approval represents the beginning of a new era of care for stage 2 type 1 diabetes patients in China, one focused on the potential of Tzield to prevent the natural progression of T1D by its unique beta-cell function preserving capabilities,"* said **Olivier Charmeil**, Executive Vice President, General Medicines, Sanofi. *"Tzield is the first approved advanced therapy that slows down the loss of beta cell function, potentially giving people living with stage 2 T1D more time without the daily treatment burden. We are proud to bring this innovative medicine to China, and we remain committed to working with local stakeholders to advance diabetes care."*

The approval aligns with recent Chinese expert consensus guidelines that recognize the importance of protecting beta-cell function as a pivotal component in the management of autoimmune T1D. These guidelines, published in November 2024, highlighted Tzield's potential therapeutic value, which has now been validated by this approval, demonstrating Tzield's relevance in addressing this significant clinical unmet need in the treatment of autoimmune T1D.

Tzield is approved for the treatment of adult and pediatric individuals aged eight years and older, living with stage 2 type 1 diabetes, in the US, the UK, Canada, Israel, the Kingdom of Saudi Arabia, the United Arab Emirates, and Kuwait. Regulatory reviews are ongoing in the EU and other jurisdictions around the world.

About Tzield

Tzield (teplizumab) is a CD3-directed monoclonal antibody. Tzield is the first and only disease modifying therapy 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. Today, it is also approved in China, the UK, 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-cells remain (it's been estimated that the 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

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