News Releases

Health Canada has granted approval for Tzield®, the first and only disease-modifying therapy in autoimmune type 1 diabetes in Canada

- Tzield® is demonstrated to delay by a median of 2 years the onset of Stage 3 type 1 diabetes in patients 8 years of age and older currently with Stage 2[1].
- In Canada, an estimated 300,000 people live with type 1 diabetes (T1D), with over 70% of new T1D diabetes diagnoses being in adults[2].

Toronto, May 5, 2025 – Health Canada has issued a Notice of Compliance (NOC) for Tzield® (teplizumab), a first-in-class disease-modifying therapy for autoimmune type 1 diabetes (T1D), that delays the onset of Stage 3 T1D in adult and pediatric patients 8 years of age and older currently living with Stage 2 type 1 diabetes[3].

The Health Canada approval for Tzield® is based on positive results from the initial Phase 2 TN-10 trial, evaluating the use of Tzield® to delay the onset of Stage 3 T1D in adults and children aged 8 years of age and older with Stage 2 T1D. The Tzield® product monograph includes clinical data which shows that patients receiving Tzield® had a median delay of 24 months to Stage 3 type 1 diabetes.

Jessica Diniz
President and CEO, Breakthrough T1D Canada
"The approval of the first disease-modifying therapy for type 1 diabetes in Canada is a milestone for our community, after supporting research on this challenge for many years. Delaying the need for insulin therapy will significantly benefit those with early-stage type 1 diabetes, their families, and the healthcare system. It will provide much-needed time to prepare for and understand disease management and reduce fears of complications."

Dr. Remi Rabasa-Lhoret
Endocrinologist
"Tzield®'s approval marks a paradigm shift in type 1 diabetes care.As the first disease-modifying therapy for autoimmune T1D, Tzield® has the potential to delay the progression of the disease, offering a new approach beyond symptom management. The clinical data[4] shows patients may gain extra time before facing the burden of everyday type 1 diabetes management, which is valuable for everyone living with type 1 diabetes or involved in their care."

Dr. Karen McAssey
Pediatric Endocrinologist
"The approval of Tzield® represents a significant scientific advancement in how we approach type 1 diabetes. For the first time, we have a therapy that can potentially delay the onset of clinical disease in children as young as 8 years old with Stage 2 type 1 diabetes. This additional time before insulin dependence could be transformative for young patients and their families, allowing them more time to adjust to their diagnosis and prepare for disease management."

Linda Santi
General Manager, General Medicines, Sanofi Canada
"The approval of Tzield® in Canada is a critical step forward in advancing diabetes care to improve the lives of Canadians at risk of developing and living with autoimmune type 1 diabetes. This approval builds upon over a century of Sanofi's leadership in leveraging our deep understanding of the immune system and reinforcing our commitment to improve and advance outcomes for people living with type 1 diabetes."

About Tzield®
Tzield® is a CD3-directed monoclonal antibody, designed to bind to the T cells responsible for the autoimmune attack of the insulin producing cells, partially stimulating and exhausting them, which preserves the pancreatic beta cells for longer. Tzield® has been approved under the same brand name and indication in the US, Israel, UAE, Kuwait, and the Kingdom of Saudi Arabia.

About autoimmune T1D
T1D is a lifelong autoimmune disease in which the immune system mistakenly attacks the insulin-producing cells (beta cells) of the pancreas, leading to high blood sugar levels. Without insulin, the body is unable to regulate blood glucose levels which leads to common symptoms associated with autoimmune T1D such as increased thirst, frequent urination, unexplained weight loss and generalized fatigue. If untreated, T1D is life-threatening.

In Canada, there are an estimated 300,000 people living with type 1 diabetes, with over 70% of new T1D diabetes diagnoses being in adults. Over 80% of Canadians living with T1D are aged 18+[5].

Autoimmune T1D manifests in three stages. It is possible to diagnose T1D early by identifying two or more autoimmune T1D-related autoantibodies in the blood and measuring the increase of blood glucose levels.

- At Stage 1, the autoimmune attack on the beta cells by the immune system has started, but blood glucose levels remain normal as there are still a significant number of working insulin producing cells. There are no visible signs or symptoms.
- At Stage 2, the immune system continues to attack the insulin producing cells, diminishing their number. Blood sugar levels are outside the normal range. However, there are still no visible signs or symptoms.
- At Stage 3, the number of functioning insulin producing cells is low, therefore, the body is no longer able to regulate its blood sugar levels. Most people will develop visible signs and symptoms, and daily, lifelong insulin therapy is required.

About TN-10 [6]
TN-10 (NCT 01030861) was a Phase 2 randomized, double-blind, event driven, placebo controlled clinical trial which evaluated teplizumab for the delay of T1D (Stage 3, or clinical T1D) in Stage 2 T1D patients, defined by the presence of two or more T1D-related autoantibodies and dysglycemia. Seventy-six patients (TZIELD® N=44, placebo N=32) were enrolled ages 8 to 49, with 72% under the age of 18, and randomized to receive a single 14-day course of either teplizumab or placebo by IV infusion.

About Sanofi
Sanofi is an R&D-driven, AI-powered biopharma company guided by our purpose: we chase the miracles of science to improve people's lives. We apply our deep understanding of the immune system to advance breakthrough science and transform the lives of millions through innovative medicines and vaccines. We are accelerating the pace of discovery, development and delivery of new and differentiated treatments to patients and are investing in our business to drive long-term sustainable growth, including state-of-the-art manufacturing and supply capabilities.

In Canada, we employ over 2,000 people and invest 20% of our revenue annually in biopharma research, representing $1.2 billion CAD in R&D over the last decade, creating jobs, business, and opportunity throughout the country. We are on track to deliver over $2 billion in new infrastructure investments by 2028, including two new vaccine manufacturing facilities at our Toronto Campus. We work in collaborative partnerships with a vast network of healthcare stakeholders and are committed to creating a healthier future in Canada.

2025 marks our 111th year dedicated to developing innovative health solutions for Canadians. What started as a small laboratory in May of 1914, recognized for having advanced some of the greatest contributions to public health, both nationally and globally, has evolved to become the largest biomanufacturing facility in Canada.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

For more information and media inquiries, please contact:
Bethany Rubin | +1 437-518-4769 | bethany.rubin@sanofi.com
Julien Guyomard |+1 416-434-3134 | julien.guyomard@sanofi.com

---

[1] **Herold KC, et al. *N Engl J Med.* 2019;381(7):603-613.** https://www.nejm.org/doi/10.1056/NEJMoa1902226?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[2] Facts and Figures. https://breakthrought1d.ca/t1d-basics/facts-and-figures/

[3] Tzield®. Product Monograph. Sanofi. April 2025

[4] Tzield®. Product Monograph. Sanofi. April 2025

[5] Facts and Figures. https://breakthrought1d.ca/t1d-basics/facts-and-figures/

[6] **Herold KC, et al. *N Engl J Med.* 2019;381(7):603-613.** https://www.nejm.org/doi/10.1056/NEJMoa1902226?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

---