CLOSER LOOK

MEMORANDUM

FDA approves Sanofi's Tzield (teplizumab) to delay the onset of stage 3 T1D in children aged one year and older (compared to eight years and older) with "stage 2" T1D – April 22, 2026

Expands initial indication for eight years and older; follows receipt of priority review by the FDA in January 2026, based on positive results from the phase 4 PETITE-4 T1D trial

Sanofi announced today that the FDA has approved Tzield (teplizumab) to delay the onset of stage 3 T1D in children aged one year and above who have been diagnosed with stage 2 T1D.[1] This approval expands Tzield's initial indication from November 2022 to include delaying T1D in those aged eight years and older.

The review for an expanded indication of Tzield received priority review by the FDA in January 2026, based on positive results from the phase 4 PETITE-4 T1D study (n=20). In 4Q25, Sanofi shared expectations for a regulatory decision by April 29, 2026 – it's great to see this was approved on an expedited (if slightly) timeline.

Tzield is also being considered for stage 3 T1D in adults and adolescents aged eight years and older – see below for more on this.

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Expanded approval of Tzield based on positive results of the PETITE 4 trial

The expanded indication of Tzield is based on positive results from the phase 4 PETITE-4 T1D study (n=20), which is expected to be fully completed in August 2026. One-year data from the trial were published in *Diabetologia* in November 2025. Primary endpoints included treatment-emergent adverse events (TEAEs), TEAEs causing treatment discontinuation, and serious adverse events (SAEs). Other endpoints assessed included immunogenicity, pharmacokinetics, pharmacodynamics, and the time from study treatment to the onset of stage 3 T1D.

The mean participant age was 4.8 years, and the median follow-up was 52 weeks. Results showed that all participants experienced at least one TEAE, with most being mild to moderate. Three participants had TEAEs leading to the discontinuation of Tzield, including anemia, elevated liver enzymes, and rash. Two participants each had two SAEs. Overall, at the time of the interim analysis, nearly 90% of participants had not progressed to stage 3 T1D, with only two participants (8.6%) progressing.

Tzield received delayed priority review for stage 3 T1D earlier this year

Tzield is also under review for individuals recently diagnosed with stage 3 T1D aged eight years or older. Tzield previously received an expedited review through the CNPV pilot program in October 2025, supported by results from the phase 3 PROTECT study (n=328), which met its primary endpoint evaluating the preservation of beta cell function. Specifically, 95% of participants who received Tzield treatment maintained peak C-peptide levels ≥0.2 pmol/mL, compared with 79% of those who received placebo.

Yet, in January 2026, the FDA announced that it had delayed its review of Tzield for stage 3 T1D due to an investigation into whether the therapy was associated with a potential treatment-related death. In 4Q25, Sanofi shared that a regulatory decision is still expected in 1H26.

Regulatory approval for Tzield outside of the US, along with ongoing trials

Tzield is also approved in the EU (under the brand name Teizeild), the UK, China, Canada, Israel, Saudi Arabia, the UAE, Kuwait, and Brazil to delay the onset of stage 3 T1D in adults and pediatric patients eight years and older diagnosed with stage 2 T1D. The timeline for regulatory reviews of Tzield's indication to delay stage 3 T1D as young as one year is unclear for regions outside the US.

In clinical trials, Sanofi launched a phase 3 BETA PRESERVE trial (n=723) in August 2025 across the US and UK for Tzield in individuals ≤25 years with stage 3 T1D and on insulin therapy. The study is currently enrolling and will measure changes in glycemic levels and prandial insulin independence over 52 weeks with Tzield compared with placebo. The trial is expected to complete in December 2028. Tzield is also being studied in the phase 3 PROTECT Extension trial (n=188) for long-term safety and efficacy in people recently diagnosed with stage 3 T1D, with expected completion in November 2026.

Next steps for TZield – a potential indication for use in stage 3 T1D

As we've written about in some depth previously (see here), Tzield is also being considered for stage 3 T1D (when people have been formally diagnosed in the "traditional" sense of needing insulin daily, etc.) in adults and adolescents aged eight years and older. As a reminder, Sanofi received the Commissioner's National Priority Voucher (CNPV) in October 2025 for this indication, and we look forward to hearing a further update on the FDA's plans sometime soon, perhaps even on Sanofi's call taking place on Wednesday, April 23! That said, we certainly know that the FDA is very under-resourced, so if this review took longer than this, that would not be surprising from our view.

Close Concerns' Questions

1. How might awareness-building, education, and marketing change around TZield as a result of this announcement, if at all?
2. Given Sanofi's commitment to long-term efficacy and safety, as well as monitoring, among the pediatric population following Tzield treatment, will a younger population require any different or more attentive care?
3. What new insights might the full ETITE-4 T1D offer for Tzield's expanded indication?

--by Esther Min, Monica Oxenreiter, and Kelly Close

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[1] Stages 1 and 2 T1D are referred to as "early-stage," "pre-symptomatic," or "pre-clinical" T1D. They can be identified through screening. Stage 3 refers to a diagnosis after people start showing the typical symptoms of T1D.