CLOSER LOOK

MEMORANDUM

FDA accepts Tzield (teplizumab) for priority review to expand the current age indication to those as young as one year old – January 5, 2026

Priority review based on the ongoing phase 4 PETITE-T1D trial (n=23), previously published in Diabetologia; FDA decision expected on April 29, 2026

Sanofi announced today that the FDA has accepted Tzield (teplizumab) for priority review[1] of its supplemental biologic license application (sBLA) to expand the therapy's current age indication. Tzield previously received FDA approval in November 2022 to delay the onset of stage 3 T1D in people aged eight years or older with stage 2 T1D. The sBLA seeks to expand this indication to those as young as one year old, supported by positive one-year data from the ongoing phase 4 PETITE-T1D trial (n=23) published in *Diabetologia* in November 2025. The FDA's decision is expected on April 29, 2026.

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Expedited review based on the ongoing phase 4 PETITE-T1D trial, expected to be completed later this year

The ongoing phase 4 PETITE-T1D trial is studying Tzield in children under eight years, with an expected completion date in August 2026. Interim results from the trial were published in *Diabetologia* in November 2025, which presented an analysis of participants after one year following Tzield infusion. 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 one or more 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 just two participants (8.6%) progressing.

Tzield previously received expedited review for stage 3 T1D

Today's news follows Tzield's receipt of an expedited review through the Commissioner's National Priority Voucher (CNPV) pilot program in October 2025 for individuals recently diagnosed with stage 3 T1D aged eight years or older. As a reminder, the CNPV program was first announced in June 2025 to offer a government-supported opportunity to accelerate the review timeline for drug and biological products from 10-12 months to one or two months.

Tzield received a CNPV for the treatment of stage 3 T1D based on the phase 3 PROTECT trial (n=328), which met its primary endpoint evaluating the preservation of beta cell function. In the trial, 95% of participants in the teplizumab group maintained peak C-peptide levels ≥0.2 pmol/mL, compared with 79% of those who received placebo. Moreover, patients treated with teplizumab achieved significantly higher stimulated C-peptide levels compared to those receiving a placebo.

Close Concerns' Questions

1. To what extent does Sanofi anticipate that an expanded indication will impact the uptake of Tzield?
2. What are Sanofi's priorities in terms of education around the safety and efficacy of Tzield, especially among young populations?

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

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[1] According to Sanofi's press release, a priority review is given to applications seeking approval for treatments that have the potential to provide significant improvements in the treatment, diagnosis, or prevention of serious conditions.