19 November 2025
EMADOC-1829012207-34306
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Teizeild

teplizumab

On 13 November 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Teizeild, intended for the treatment of type 1 diabetes (T1D). The applicant for this medicinal product is Sanofi Winthrop Industrie.

Teizeild is a PRIME medicine. This scheme optimises development and accelerates the evaluation of medicines that fulfil an unmet medical need, helping them to reach patients sooner.

Teizeild will be available as a 1 mg/ml concentrate for solution for infusion. The active substance of Teizeild is teplizumab, a diabetes drug (ATC code: A10XX01). Teplizumab is a humanised immunoglobulin G1 monoclonal antibody that binds to the CD3ε chain of the T cell receptor (TCR)-complex on human T lymphocytes. The mechanism of action of teplizumab is not fully understood, but it is thought to involve partial agonistic signalling and deactivation of pancreatic beta-cell autoreactive T lymphocytes.

Teizeild preserves beta cell function and delays the onset of stage 3 T1D. The main evidence for the effectiveness of Teizeild was based on a multicentre, double-blind, randomised, placebo-controlled study (TN-10) in people with stage 2 T1D at high risk for progressing to stage 3 T1D. The study showed that the median time to progression to stage 3 T1D was 49.5 months in the Teizeild group, compared with 24.9 months in the placebo group.

The most frequently reported adverse reactions were lymphopenia, leukopenia, neutropenia and rash. The most frequent serious adverse reaction was cytokine release syndrome.

The full indication is:

Teizeild is indicated to delay the onset of stage 3 type 1 diabetes (T1D) in adult and paediatric patients 8 years of age and older with stage 2 T1D.

Teizeild should be administered by a healthcare professional with access to appropriate medical support to manage potential severe adverse reactions.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.