Anti-Human CD3 (Teplizumab)

IVMB0474

Product Information

Product SKU:	IVMB0474	**Clone**:	PRV-031	**Target**:	CD3
Size:	1 mg, 50 mg, 100 mg, 5 mg, 25 mg			**Isotype**:	Human IgG1κ

Additional Information

Reactivity:	Human	**Host Species**:	Human
Antibody Type:	Biosimilar Recombinant Human Monoclonal Antibody	**Expression Host**:	HEK-293 Cells

Immunogen Information

Background:

Type I diabetes is a chronic autoimmune disease that destroys insulin-producing beta-cells in the islets of Langerhans, leading to a dependence on exogenous insulin for survival[1]. Teplizumab (TZIELD) is a humanized, anti-CD3ε IgG1κ monoclonal therapeutic that delays the onset of Stage 3 Type 1 diabetes[1], [2]. CD3ε plays an essential role in T cell development and is part of the T cell-receptor CD3-complex, which acts as an external signal transducer[3]. Defects in CD3ε cause immunodeficiency and have been linked to susceptibility to type I diabetes in women.

Teplizumab is an Fc receptor-nonbinding anti-CD3 antibody[4] whose Fc region is mutated (L234A; L235A) to reduce effector functions[2]. When Teplizumab is administered by intravenous infusion once daily for 14 consecutive days, it reduces the loss of beta-cell function[1]. Teplizumab treatment modifies CD8+ T lymphocytes, which are thought to kill beta-cells, to display a partially exhausted phenotype associated with delayed disease progression[1], [5]. Teplizumab delays the median onset of Stage 3 Type 1 diabetes by 2 years compared to placebo[1], [2]. Additionally, the effects of treatment persist over time. The median years to diabetes diagnosis after Teplizumab treatment is ~ 5 years compared to ~ 2 years in the placebo-treated group[6].

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In November 2022, the United States Food and Drug Administration approved Teplizumab injection to delay the onset of Stage 3 Type 1 diabetes in adults and pediatric patients aged 8 years and older who have Stage 2 Type 1 diabetes[7].

Endotoxin Level: < 1.0 EU/mg as determined by the LAL method

Applications: ELISA

Synonyms: Teplizumab, CD3ε, 876387-05-2

Antigen Distribution: CD3 is found on the surface of mature T cells.

Immunogen: Human CD3

Formulation: This biosimilar antibody is aseptically packaged and formulated in 0.01 M phosphate buffered saline (150 mM NaCl) PBS pH 7.2 - 7.4 with no carrier protein, potassium, calcium or preservatives added. Due to inherent biochemical properties of antibodies, certain products may be prone to precipitation over time. Precipitation may be removed by aseptic centrifugation and/or filtration.

Specificity: This non-therapeutic biosimilar antibody uses the same variable region sequence as the therapeutic antibody Teplizumab. This product is for research use only. Teplizumab activity is directed against CD3 expressed on mature T cells.

Product Preparation: Recombinant biosimilar antibodies are manufactured in an animal free facility using onlyin vitroprotein free cell culture techniques and are purified by a multi-step process including the use of protein A or G to assure extremely low levels of endotoxins, leachable protein A or aggregates.

Storage & Handling: Functional grade biosimilar antibodies may be stored sterile as received at 2-8°C for up to one month. For longer term storage, aseptically aliquot in working volumes without diluting and store at -80°C. Avoid Repeated Freeze Thaw Cycles.

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