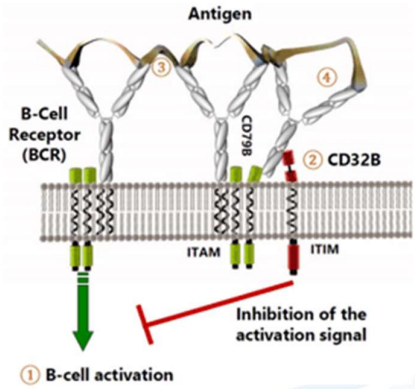
TEPLIZUMAB

- intravenous infusions

Monoclonal antibody (anti-CD3) an investigational candidate preserve beta cell function and delayed the onset of Type 1 diabetes.

Generic Name	teplizumab
Date Designated	09/29/2006
Orphan Designation	Treatment of recent-onset Type I diabetes
Orphan Designation Status	Designated
FDA Orphan Approval Status	Not FDA Approved for Orphan Indication

Granted Breakthrough Therapy Designation by the USFDA and PRIME designation by the European Medicines Administration



Source: company presentation

Provention Bio wins FDA panel backing for teplizumab - first disease-modifying therapy for Type I Diabetes (T1D)

- **It is highly anticipated that Teplizumab will be approved and will be especially beneficial for pediatric population. The next (PDUFA) action date is July 2, 2021.**
- **Teplizumab improves and stabilizes beta cell function in antibody-positive high-risk individuals**

- **Blockbuster market potential. Over 1.6 million Americans have T1D.**
- **This Mab has the potential to address several B-cell centric autoimmune conditions - Lupus, rheumatoid arthritis and multiple sclerosis, as well as orphan diseases such as idiopathic thrombocytopenic purpura, neuromyelitis optica, pemphigus or myasthenia gravis.**

Limitation: Current Clinical Trials majorly conducted on Caucasian patients, does not include patients of other races. Safety profiles need more investigation - **long-term malignancies, including the risk of diabetic ketoacidosis (DKA)**

Probability of this drug being approved in developing nations and other countries in near future is not foreseen due to limited population