# Registry for Stage 2 Type 1 Diabetes

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age:
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

TZIELD-Exposed Cohort

- Patients in the US diagnosed with Stage 2 T1D who are planned to initiate TZIELD treatment according to the currently approved label or who have initiated TZIELD treatment within 6 months prior to enrollment:
- Day 1: 65 mcg/m2
- Day 2: 125 mcg/m2
- Day 3: 250 mcg/m2
- Day 4: 500 mcg/m2
- Days 5 through 14: 1,030 mcg/m2 per day
- Cumulative dose is approximately 11,240 mcg/m2
- Appropriate written informed consent/assent as applicable for the age of the patient

TZIELD-Unexposed Cohort

- Patients in the US diagnosed with Stage 2 T1D but who are not treated with TZIELD
- Appropriate written informed consent/assent as applicable for the age of the patient

Exclusion Criteria:

- Patients who initiated TZIELD treatment more than 6 months prior to enrollment
- Patients who had participated in a previous clinical trial for TZIELD
- Patients in an ongoing clinical trial of an investigational product or who had ended participation within 6 months prior to study enrollment; patients participating in other observational studies may be enrolled

The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.

## Conditions & Interventions

Interventions:
DRUG: TZIELD (teplizumab-mzwv)
Conditions:
Type 1 Diabetes

## More Information

Description:
Stage 2 Type 1 Diabates (T1D) is an early stage of T1D characterized by dysglycemia but not yet leading to clinical symptoms. Progression of the disease to Stage 3 (clinical T1D), leads to overt hyperglycemia requiring eventually exogenous insulin. TZIELD® (teplizumab-mzwv) has been approved to delay onset of stage 3 T1D, by the United States (US) Food and Drug Administration (FDA) for adults and children aged 8 years and older with Stage 2 T1D. The purpose of this study is to collect general information on patients with stage 2 T1D and further information on the long-term effects of TZIELD® in patients with Stage 2 T1D, treated as per standard of care.

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