Provention Bio invites you to attend a Hybrid program titled

TZIELD™ (teplizumab-mzwv): Potential to Delay Stage 3 T1D

PRESENTED BY:

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University Hospitals

HOSTED BY:

Rebecca Stawicki
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INDICATION

TZIELD™ (teplizumab-mzwv) is a CD3-directed monoclonal antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D.

SELECT IMPORTANT SAFETY INFORMATION

- **Cytokine Release Syndrome (CRS):** CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. Prior to TZIELD treatment, premedicate with antipyretics, antihistamines and/or antiemetics, and treat similarly if symptoms occur during treatment. If severe CRS develops, consider pausing dosing for 1 day to 2 days and administering the remaining doses to complete the full 14-day course on consecutive days; or discontinue treatment. Monitor liver enzymes during treatment. Discontinue TZIELD treatment in patients who develop elevated alanine aminotransferase or aspartate aminotransferase more than 5 times the upper limit of normal (ULN) or bilirubin more than 3 times ULN.

Please see additional Important Safety Information below.

The program takes place on Friday, September 29, 2023 at 07:45 AM CT. Please RSVP to this program using the link below.

https://rsvp.proventionbio.cm-go.com/home/index/PR-07201

PROGRAM DATE AND TIME

Friday, September 29, 2023, 07:45 AM CT

PROGRAM LOCATION

Radisson Hotel & Conference Center
2040 Airport Drive, Ashwaubenon, Wisconsin 54313-5538
This program is also hosted virtually
Webcast Link:

https://us06web.zoom.us/meeting/register/tZAkfu6urTItGN0TaA6hRfQ-KKDCffFmTneD
Access Code:
Phone:

IMPORTANT SAFETY INFORMATION CONTINUED

WARNINGS AND PRECAUTIONS

- **Serious Infections:** Use of TZIELD is not recommended in patients with active serious infection or chronic infection other than localized skin infections. Monitor patients for signs and symptoms of infection during and after TZIELD administration. If serious infection develops, treat appropriately, and discontinue TZIELD.

- **Lymphopenia:** Lymphopenia occurred in most TZIELD-treated patients. For most patients, lymphocyte levels began to recover after the fifth day of treatment and returned to pretreatment values within two weeks after treatment completion and without dose interruption. Monitor white blood cell counts during the treatment period. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), discontinue TZIELD.

- **Hypersensitivity Reactions:** Acute hypersensitivity reactions including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in TZIELD-treated patients. If severe hypersensitivity reactions occur, discontinue TZIELD and treat promptly.

- **Vaccinations:** The safety of immunization with live-attenuated (live) vaccines with TZIELD-treated patients has not been studied. TZIELD may interfere with immune response to vaccination and decrease vaccine efficacy. Administer all age-appropriate vaccinations prior to starting TZIELD.
    - Administer live vaccines at least 8 weeks prior to treatment. Live vaccines are not recommended during treatment, or up to 52 weeks after treatment.
    - Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment. Inactivated vaccines are not recommended during treatment or 6 weeks after completion of treatment.

ADVERSE REACTIONS: Most common adverse reactions (>10%) were lymphopenia, rash, leukopenia, and headache.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm.
- **Lactation:** A lactating woman may consider pumping and discarding breast milk during and for 20 days after TZIELD administration.

Please see accompanying Prescribing Information, including patient selection criteria, and Medication Guide.

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