COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 220

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Tzield™: First Disease-Modifying Therapy in Type 1 Diabetes

The U.S. Food and Drug Administration (FDA) has approved Provention Bio's Tzield™ (teplizumab-mzwv) as a first-in-class treatment to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with Stage 2 T1D.

Clinical Review:

T1D is an autoimmune condition in which the pancreas does not produce enough insulin. According to the Centers for Disease Control and Prevention (CDC), approximately 5% to 10% of people with diabetes have type 1. T1D usually develops in children, teenagers, and young adults, but could happen at any age. Patients who have a genetic susceptibility to developing T1D progress through stages before developing overt hyperglycemia requiring insulin treatment.

- **Stage 1:** appearance of autoantibodies
- **Stage 2:** involves dysglycemia
- **Stage 3:** autoimmune destruction of beta cells has occurred (blood glucose is elevated and patients are symptomatic and require insulin treatment)

Interventions at Stage 1 or Stage 2 may delay the progression to Stage 3 T1D.

Efficacy:

Tzield™ (teplizumab-mzwv) is the first FDA-approved pharmacological therapy for delaying the onset of clinical T1D. It is an anti-CD3-directed antibody designed to bind to certain immune system cells and delay progression to Stage 3 T1D. The efficacy was demonstrated in the pivotal Phase 2 multicenter TN-10 trial. The study included 76 patients 8 to 49 years of age with stage 2 T1D. Patients were randomly assigned to receive teplizumab-mzwv once daily via intravenous infusion (n=44) or placebo (n=32) for 14 days. The primary endpoint was the time from randomization to development of stage 3 type 1 diabetes diagnosis. After a median follow-up time of 51 months, 45% (n=20) of patients treated with teplizumab-mzwv developed stage 3 type 1 diabetes compared with 72% (n=23) of patients treated with placebo. Treatment with teplizumab-mzwv demonstrated a statistically significant delay in the development of stage 3 type 1 diabetes (hazard ratio, 0.41; 95% CI, 0.22-0.78; P =.0066).

Safety:

Adverse reactions occurring in >5% of patients in the teplizumab-mzwv arm included lymphopenia (73%), rash (36%), leukopenia (21%), headache (11%), neutropenia (5%), increased alanine aminotransferase (5%), nausea (5%), diarrhea (5%), and nasopharyngitis (5%).

Dosing:

Tzield™ is administered intravenously using a body surface area-based dosing, once daily for 14 consecutive days as follows:

- Day 1: 65mcg/m^2
- Day 2: 125mcg/m^2
- Day 3: 250 mcg/m^2
- Day 4: 500mcg/m^2
- Day 5 through 14: 1,030mcg/m^2

There should be confirmation that the patient has Stage 2 type 1 diabetes by documenting:

- At least two positive pancreatic islet cell autoantibodies
- Dysglycemia without overt hyperglycemia using an oral glucose tolerance test

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3. Myshko, D. (2022, November 18). *FDA approves first drug that delays diabetes*. Formulary Watch. https://www.formularywatch.com/view/fda-approves-first-drug-that-delays-diabetes

2 Street 1, Suite 500
Guaynabo, PR 00968
Tel. 787.522.5252
Fax 866.912.2830
www.pharmpix.com
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