Press Release, December 8, 2022

Update: Diamyd Medical's CEO clarifies comments on the recent approval by FDA of Provention Bio´s drug candidate Teplizumab

This updated press release describes teplizumab according to the approved FDA label. Updates in italics.

"The FDA approval of teplizumab is great news for the entire autoimmune diabetes field," comments Ulf Hannelius, CEO of Diamyd Medical. "The approval creates clarity around the regulatory pathway for disease-modifying therapies in Type 1 Diabetes and will set a reference for the field regarding pricing and reimbursement. This is important and valuable for the antigen-specific immunotherapy Diamyd®, the first ever precision medicine therapeutic for Type 1 Diabetes in Phase 3 development."

Provention Bio's drug Teplizumab is a CD3-directed monoclonal antibody expected to be given as a daily intravenous infusions over a 14-day period. The US Food and Drug Administration has approved teplizumab as a *treatment 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*. FDA describes its mechanism of action as "*Teplizumab may deactivate the immune cells that attack insulin-producing cells, while increasing the proportion of cells that help moderate the immune response."*

FDA further writes:

"Tzield's safety and efficacy were evaluated in a randomized, double-blind, event-driven, placebo-controlled trial with 76 patients with stage 2 type 1 diabetes. In the trial, patients randomly received Tzield or a placebo once daily via intravenous infusion for 14 days. The primary measure of efficacy was the time from randomization to development of stage 3 type 1 diabetes diagnosis. The trial results showed that over a median follow-up of 51 months, 45% of the 44 patients who received Tzield were later diagnosed with stage 3 type 1 diabetes, compared to 72% of the 32 patients who received a placebo. The mid-range time from randomization to stage 3 type 1 diabetes diagnosis was 50 months for the patients who received Tzield and 25 months for those who received a placebo. This represents a statistically significant delay in the development of stage 3 type 1 diabetes.

The most common side effects of Tzield include decreased levels of certain white blood cells, rash and headache. The use of Tzield comes with warnings and precautions, including premedicating and monitoring for symptoms of Cytokine Release Syndrome; risk of serious infections; decreased levels of a type of white blood cell called lymphocytes; risk of hypersensitivity reactions; the need to administer all age-appropriate vaccinations prior to starting Tzield; as well as avoiding concurrent use of live, inactivated and mRNA vaccines with Tzield. "

For more information on the approval of teplizumab see https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1-diabetes.

Diamyd Medical's confirmatory Phase 3 trial DIAGNODE-3 (https://diagnode-3.com/) assesses three single injections of Diamyd® given one month apart and is actively recruiting patients with recent-onset clinical Type 1 diabetes in eight European countries. Diamyd® is an antigen-specific tolerizing beta-cell preserving therapeutic, which has not shown any major safety signals, or immunosuppressive effects in over 15 clinical studies.

About Diamyd Medical
Diamyd Medical develops precision medicine therapies for Type 1 Diabetes. Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruting pateients with recent-onset Type 1 Diabetes in eight European countries. Significant results have previously been shown in a large genetically predefined patient group in a large-scale meta-analysis as well as in the Company's European Phase IIb trial DIAGNODE-2, where the Diamyd® was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. A manufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the antigen-

specific immunotherapy Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. An investigator-initiated Remygen® trial in individuals living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB as well as in the artificial intelligence company MainlyAI AB.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

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