Press Release, November 18, 2022

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

"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 it for the delay of clinical Type 1 Diabetes in at-risk individuals (with so-called Stage 2 Type 1 Diabetes, i.e. the presence of at least two islet autoantibodies and dysglycemia but without overt symptoms and/or hyperglycemia).

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. In contrast, Teplizumab is an immunosuppressive treatment. The use of teplizumab comes with warnings and precautions. 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.

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 diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. A vaccine manufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine 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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