Press Release, December 6, 2022

Diamyd Medical precision medicine patent for prevention and treatment of autoimmune diabetes to be granted in Eurasia

The patent to be granted by the Eurasian Patent Office is valid until 2035. It primarily protects the use of a GAD autoantigen to treat or prevent autoimmune diabetes in individuals carrying the HLA DR3-DQ2 gene. GAD is the active component in the antigen-specific immunotherapy Diamyd® that is being evaluated in the confirmatory Phase III trial DIAGNODE-3.

The countries included in the Eurasian cooperation are Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan and Turkmenistan.

HLA DR3-DQ2, associated with autoimmunity against GAD, represents one of the most common genetic risk factors for Type 1 Diabetes since up to 40% of individuals with the disease carry the gene. A large-scale meta-analysis published in *Diabetologia* in 2020 showed that positivity for HLA DR3-DQ2 is associated with clinical response to the antigen-specific immunotherapy Diamyd®. This was prospectively confirmed in the Phase IIb trial DIAGNODE-2, published in *Diabetes Care* in May 2021. Additional follow-up analyses published in *Diabetes, Obesity & Metabolism* and *The Journal of Clinical Endocrinology & Metabolism* in 2022 further showed that the therapeutic effect of Diamyd® on preserving endogenous insulin production associates with a statistically significant and clinically relevant effect on improving blood glucose control.

The patent has in additon to Eurasia also been granted in Europe, with additional countries pending. Diamyd Medical holds, as part of an exclusive license from the University of California, Los Angeles (UCLA), patent protection in the United States, which is valid until 2032 for the treatment of diabetes with GAD, a major autoantigen in autoimmune diabetes. Diamyd Medical also holds patent protection valid until 2035 in Europe, China, Japan, Russia, Israel and Australia for intralymphatic administration of Diamyd®, the administration route used in the ongoing confirmatory Phase III trial with Diamyd®. As a biological drug, Diamyd® will, independently of patent protection, enjoy twelve and ten years market exclusivity from the date of market approval in the US and Europe respectively.

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 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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