



Press Release, October 11, 2021

The diabetes vaccine Diamyd® to be featured in two oral presentations at the International Diabetes Federation Congress

Two abstracts, highlighting clinical results that showed improved glycaemic control following treatment with Diamyd® (GAD-alum) as well as the design of the precision medicine Phase III trial DIAGNODE-3, have been elected for oral poster presentations at the International Diabetes Federation Congress (IDF) to be held as a digital event on December 6-11, 2021. The abstracts will be presented by Professor Johnny Ludvigsson, Linköping University, and Ulf Hannelius, CEO of Diamyd Medical.

“It is a great honor and a testament to the importance of our work that the therapeutic diabetes vaccine Diamyd® is attracting more and more interest and receives this level of attention at such a prestigious international conference”, says Ulf Hannelius, CEO of Diamyd Medical.

The first presentation is titled “Intralymphatic GAD-Alum (Diamyd®) improves glycaemic control in Type 1 diabetes patients carrying HLA DR3-DQ2”, and will be presented by Professor Johnny Ludvigsson. The presentation summarizes results from the Phase IIb trial DIAGNODE-2 where individuals with type 1 diabetes who carry the gene HLA DR3-DQ2, 15 months after study start, measured significantly shorter time with elevated blood glucose level (unadjusted p-value 0.0043) and significantly more time with normal blood glucose level (unadjusted p-value 0.0075) after treatment with Diamyd® than subjects treated with placebo.

The second presentation is titled “Design of a precision medicine GAD-alum immunotherapy Phase III clinical trial in Type 1 Diabetes”, and will be presented by Ulf Hannelius. As previously communicated, the best effect of the therapeutic diabetes vaccine Diamyd® is seen in individuals that are positive for the HLA DR3-DQ2 gene and simultaneously negative for the HLA DR4-DQ8 gene, the so-called Super-responder group. The Phase III trial, DIAGNODE-3, is designed to formally assess, with high statistical power, the treatment effect in both the full patient population of individuals that carry the DR3-DQ2 gene as well as in the Super-responder subgroup (about half of the full patient population in the trial).

In addition to the oral presentations at IDF 2021 (<https://idf2021.org/>), the abstracts will also be published in the official journal of the International Diabetes Federation; “Diabetes Research and Clinical Practice”.

The International Diabetes Federation (IDF) is an umbrella organization of over 230 national diabetes associations in 170 countries and territories. It represents the interests of the growing number of people with diabetes and those at risk. The Federation has been leading the global diabetes community since 1950.

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have 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. Preparations for a confirmatory Phase III trial in the US and Europe are on-going, to start recruiting patients later in 2021. 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 patients 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.

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; phone: +46 8-528 00 399, e-mail: info@fnca.se

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