



Press release, April 16, 2020

Diamyd Medical opens up for vaccine manufacturing in Umeå, Sweden

A new manufacturing facility is being set up in Umeå by Diamyd Medical. The first priority of the new site is to receive the process technology for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®.

“The importance of being in control of your own manufacturing process has never been higher”, says Ulf Hannelius, CEO of Diamyd Medical. “Taking over the GAD manufacturing technology, a key process for the company, is a strategic, long-term decision to maximize shareholder value. It provides Diamyd Medical with direct control of the technology for a potential future transfer to a pharmaceutical partner or third party manufacturer for securing supply from one or more sources if required. In short, a significant step towards building a fully integrated biopharmaceutical company“.

The 10,000 square foot site comprises clean rooms, laboratory facilities and office space. Investments, initially estimated to approximately SEK 20 million (about USD 2 million) will be allocated for systems, instruments and personnel required to set up the GAD manufacturing technology.

Diamyd Medical previously announced that it entered an agreement with its US GAD manufacturer that facilitates the transition of the manufacturing process. As part of the agreement Diamyd Medical received USD 5 million (approximately SEK 48 million) in cash.

While ongoing clinical trials with Diamyd®, including the Phase IIb trial DIAGNODE-2, progress according to plans, for execution of new trials during the technology transfer period, new Diamyd® study drug will be formulated from existing GAD protein.

About the diabetes vaccine Diamyd® compared to other technologies

Diamyd® is the world's furthest developed antigen-specific immunotherapy for autoimmune diabetes. It is also the only therapy based on the full length GAD65 protein, the antigen that patients diagnosed with type 1 diabetes and LADA most often have antibodies against. The purpose of Diamyd® is to preserve the patient's endogenous insulin production by safely and specifically reprogramming the body's immune system to tolerate GAD65. This avoids the safety issues associated with more broad acting immunosuppressive treatments that block entire immunological pathways. Moreover, while many other antigen-specific immunotherapies are based on peptides, i.e. shorter portions of, for example, insulin proteins, Diamyd® contains the entire GAD65 as an active component. This means that the whole protein is processed by the body's immune cells in a natural way, without the drug manufacturer having made assumptions about which part of the protein is the most important.

About Diamyd Medical

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Diamyd® has demonstrated good safety in trials encompassing more than 1,000 patients as well as significant effect in some pre-specified subgroups. Results from the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes, are expected to be presented in the third quarter of 2020. Diamyd Medical also develops the GABA-based investigational drug Remygen® for regeneration of endogenous insulin production. 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 and has holdings in the medtech company Companion Medical, Inc., San Diego, USA.

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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This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 18.45 CET on April 16, 2020.