



Press release, May 27, 2020

## **Results from clinical trial with Diamyd® in children at high risk for type 1 diabetes**

*Results from the investigator initiated prevention trial DiAPREV-IT 2, where 26 healthy children at high risk for type 1 diabetes have been treated with two subcutaneous injections of Diamyd® or placebo, showed that over the course of two years, one individual in the Diamyd® arm and two individuals in the placebo arm were diagnosed. No safety concerns were raised and the safety profile was comparable between the active arm and the placebo arm.*

The trial, led by Associate Professor Helena Elding Larsson, Lund University, was originally designed to follow 80 children over the course of five years. In 2017, following inconclusive results from the pilot trial DiAPREV-IT 1, it was decided that the DiAPREV-IT 2 trial should be shortened to follow 26 children for two years. Over the two year course of the trial, one individual in the Diamyd® arm and two individuals in the placebo arm were diagnosed. The two individuals in the placebo arm were diagnosed closer to baseline compared to the individual diagnosed in the Diamyd® arm. In a group of 26 children at risk for type 1 diabetes it is expected that fewer than five develop the disease during a two-year period whereby it is inappropriate to draw conclusions regarding the efficacy of the treatment. No safety concerns were raised and the safety profile was comparable between the active arm and the placebo arm. Mechanistic studies are still due to be conducted, and data from both DiAPREV-IT 1 and DiAPREV-IT 2 will be evaluated in a combined analysis.

“Safety is paramount when treating healthy children and these data once again highlight the attractiveness of evaluating antigen-specific immunotherapies like Diamyd® for delaying or preventing the diagnosis of type 1 diabetes”, says Ulf Hannelius, CEO of Diamyd Medical. “The dataset will support the design of larger prevention trials where we will be able to incorporate all the accumulated knowledge around Diamyd®, including targeting genetically defined subgroups and using ultrasound guided intralymphatic injections to further enhance the efficacy of Diamyd®.”

### **About DiAPREV-IT 2**

A placebo-controlled prevention trial led by Associate Professor Helena Elding Larsson, Lund University, where Diamyd®, with oral supplements of vitamin D, has been administered subcutaneously to 26 children at high risk of developing type 1 diabetes, meaning that they have an ongoing autoimmune process but not yet any clinical symptoms of diabetes. The aim of the trial has been to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes during a two-year follow-up period as well as to evaluate the immunological response to the treatment.

### **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. A new facility for vaccine manufacturing is being set up in Umeå with the first priority to receive the process technology 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® 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](mailto:info@fnca.se).

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