



Press release, May 7, 2019

Fully recruited European Phase IIb trial with the diabetes vaccine Diamyd®

All patients in Diamyd Medical's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine Diamyd® (rhGAD65/alum) is given directly into the lymph node, are now randomized and the trial is thus fully recruited. In total, 109 of originally 106 planned patients are included. The patients will be followed for 15 months and topline results are expected in the third quarter next year.

In the Phase IIb trial DIAGNODE-2, a total of three injections of the Diamyd® diabetes vaccine (or its placebo) are given to patients aged 12-24 years, recently diagnosed with type 1 diabetes, in order to maintain the endogenous insulin production. Topline results with analysis of the effect on the body's own insulin production, measured as meal-stimulated C-peptide, are expected to be presented during the third quarter of 2020.

“The full enrollment of DIAGNODE-2 is a significant milestone in Diamyd Medical's work to develop a treatment to slow down, stop and reverse the course of the disease in type 1 diabetes,” says Ulf Hannelius, CEO of Diamyd Medical. “If DIAGNODE-2 confirms the positive results we have seen so far in the ongoing open-label pilot trial DIAGNODE-1, we have laid the foundation for a potential earlier market application and a therapy that can radically change the treatment options for those who live with type 1 diabetes.”

The double-blind placebo-controlled diabetes trial DIAGNODE-2 is conducted at diabetes clinics in Sweden, the Czech Republic, Spain and the Netherlands and is led by Professor Johnny Ludvigsson at Linköping University.

“Treatment with Diamyd® in the lymph node can become the first disease-modifying treatment of type 1 diabetes and the first antigen-specific immunotherapy for an autoimmune disease in clinical practice,” says Professor Johnny Ludvigsson at Linköping University. “Results from the DIAGNODE-1 trial show the potential of Diamyd® to preserve natural insulin production, improve metabolic control and reduce the need for insulin therapy in patients recently diagnosed with type 1 diabetes. We hope to be able to confirm the very promising results in DIAGNODE-1 in the now fully recruited DIAGNODE-2.”

About DIAGNODE-2

The placebo-controlled trial DIAGNODE-2 encompasses 109 patients from Spain, the Czech Republic, Sweden and the Netherlands, aged 12–24 years. The patients, recently diagnosed with type 1 diabetes, are given the diabetes vaccine Diamyd® (or its placebo) directly into the lymph node on three occasions, one month apart, in combination with oral vitamin D (or its placebo) during four months, starting 30 days prior to the first injection. The patients are followed for 15 months with the aim to evaluate the remaining insulin producing capacity. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University. Sponsor for the trial is Diamyd Medical. For more information about the trial, see www.diagnode-2.com.

About type 1 diabetes

Type 1 diabetes is an autoimmune disease where the beta cells, the cells in the pancreas that produce insulin, are broken down by the immune system. GAD65 (glutamic acid decarboxylase) is an endogenous protein that is expressed by the beta cells. In autoimmune diabetes, the immune system identifies the protein as dangerous and attacks and destroys the insulin-producing cells. GAD65 is the active ingredient in the diabetes vaccine Diamyd® which is developed with the aim to reduce the immune system's sensitivity to GAD65 and thus preserving the remaining insulin production.

About Diamyd Medical

Diamyd Medical develops the diabetes vaccine Diamyd®, as 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 effect in some pre-specified subgroups. Besides the Company's own European Phase-IIb trial DIAGNODE-2 where the diabetes vaccine is administered directly into a lymph node, three investigator initiated clinical trials are ongoing with 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. An investigator-initiated trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is also ongoing at the University of Alabama at Birmingham, USA. 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 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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