



Press release, November 13, 2017

## **Phase II-trial DIAGNODE-2 ahead of World Diabetes Day now open to include patients**

*Diamyd Medical's pivotal trial DIAGNODE-2 is now open for booking patients. The diabetes vaccine Diamyd® for intralymphatic administration will be delivered to the clinics participating in the trial that can begin screening patients. DIAGNODE-2 comprises about 80 patients from Spain, the Czech Republic and Sweden between the ages of 12-24 who have been diagnosed with type 1 diabetes in the last 6 months.*

“Given the highly promising data we have seen from DIAGNODE-1, it is of course a great event and a potential opportunity for diabetes patients, and we are particularly pleased that we can start work on patient recruitment right in connection to the World Diabetes Day,” says Professor Johnny Ludvigsson, Coordinating Investigator of DIAGNODE-2.

“Our goal with DIAGNODE-2 is to finally confirm the effect of the diabetes vaccine,” says Ulf Hannelius, CEO of Diamyd Medical.

### **About type 1 diabetes and DIAGNODE-2**

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®.

In the placebo-controlled trial DIAGNODE-2, where the diabetes vaccine Diamyd® is administered directly into the lymph node, approximately 80 patients between the ages of 12-24 are included, newly diagnosed with type 1 diabetes. Patients will be monitored for 15 months to evaluate their remaining insulin producing capacity. The treatment is being tested with the goal to interrupt the autoimmune attack on the beta cells by reducing the immune system's sensitivity to GAD65 and thus preserving the remaining insulin production.

The remaining insulin production in newly diagnosed type 1 diabetes patients is important to preserve, as it facilitates life with diabetes, decreases the number of hypoglycemia and leads to fewer long-term complications. Coordinating Investigator for DIAGNODE-2 is Professor Johnny Ludvigsson at Linköping University.

### **About Diamyd Medical**

Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Besides the Company's own European Phase-II trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymph node, there are four investigator initiated clinical trials ongoing with Diamyd®. Diamyd Medical also develops Remygen®, a proprietary GMP manufactured oral GABA-based study drug. An investigator initiated placebo controlled trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is ongoing at the University of Alabama at Birmingham. Exclusive licenses for GABA and positive allosteric modulators of the GABAA receptor for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine Diamyd® and Remygen® key assets. Diamyd Medical is also 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 and in the gene therapy company Periphagen, Inc., Pittsburgh, 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.

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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 07.55 CET on November 13, 2017.