



Press release, April 23, 2018

50% enrollment milestone reached in Diamyd Medical's European Phase II trial

Half of the patients, 40 out of 80, are now included in the European Phase II trial DIAGNODE-2, where the diabetes vaccine Diamyd® is administered directly into the lymph node.

“We are very pleased with the great interest in DIAGNODE-2, and the great commitment from the 18 leading clinics in Spain, the Czech Republic and Sweden where the trial is conducted, which enables the efficient recruitment of trial participants,” says Ulf Hannelius, CEO of Diamyd Medical.

As of April 23, 54 patients have been screened to assess if they are eligible to participate in the trial. Of these, 40 have already been included in the trial. The time from which a patient has been screened, to be included in the trial is 14-28 days. About 100 patients are planned to be screened to have 80 patients included. Diamyd Medical estimates that the rate of recruitment is in line with the target; fully recruited trial in November 2018.

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® being developed with the aim to reduce the immune system's sensitivity to GAD65 and thus preserving the remaining insulin production.

About DIAGNODE-2

The placebo-controlled trial DIAGNODE-2 encompasses approximately 80 patients from Spain, the Czech Republic and Sweden, 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.

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. Diamyd® has demonstrated good safety in studies with more than 1,000 patients as well as effect in some pre-specified subgroups. 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™, an 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 GABA receptors 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 10:00 CET on April 23, 2018.