



Press Release, March 12, 2018

Interim report from DIAGNODE-1 shows continued positive clinical course

Diamyd Medical today announced that a sixth interim report from the investigator initiated DIAGNODE-1 trial, an open label clinical pilot trial in which the diabetes vaccine Diamyd® is given directly into the lymph node, shows a continued positive clinical course in terms the patients' own ability to produce insulin as well as long-term blood sugar and insulin dose when nine patients have been followed for 15 months.

In a sixth interim report from the open label investigator initiated clinical pilot trial DIAGNODE-1, where the diabetes vaccine Diamyd® is administered directly into the lymph node, results are now presented when nine out of twelve patients have been followed for 15 months. Safety continues to look good and no serious side effects have been reported. On average, the patients' own insulin production (measured as stimulated C-peptide, AUC) decreased by 10.4% while fasting C-peptide increased by 15%. Meanwhile, HbA1c and insulin doses have decreased by 24% and 19%, respectively. Overall, this indicates that the disease progression is still positive at 15 months for these nine patients and is in line with previously reported results from the trial.

About DIAGNODE-1

DIAGNODE-1 is an open label clinical pilot trial, comprising a total of twelve patients between the ages of 12 and 30 with type 1 diabetes, where the diabetes vaccine Diamyd® is administered three times, one month apart, in a low (4µg) dose directly into the lymph node. The treatment is combined with oral vitamin D. All twelve patients have been followed for 6 months. Nine patients (three new patients) have been followed for 15 months and out of these have four been followed for the whole trial period, 30 months. All twelve patients will have performed their 15-month visit at the end of the summer. In addition to 15-month results for all patients, Diamyd Medical will monitor the trial at earlier times prior to meetings with potential partners.

About DIAGNODE-2

The preliminary results in DIAGNODE-1 which demonstrated a positive clinical progression and desired immunological response are followed up by the clinical trial DIAGNODE-2. DIAGNODE-2 is a placebo-controlled trial comprising approximately 80 patients from Sweden, the Czech Republic and Spain, aged 12–24 years, recently diagnosed with type 1 diabetes. 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. Diamyd Medical is Sponsor of the trial.

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 08:17 CET on March 12, 2018.