



Press release, December 11, 2017

## The diabetes vaccine Diamyd® shows positive results

*Diamyd Medical today announced results from DIAGNODE-1, when all patients have been followed for 6 months. A clinically relevant and positive progression can be demonstrated in terms of the body's own capacity to produce insulin, as well as long-term blood sugar and insulin dose. No serious adverse events have been reported.*

"The results seen in DIAGNODE-1 are gratifying, now that all twelve patients have been followed for 6 months," says Johnny Ludvigsson, Professor at Linköping University and Sponsor of the trial. "It is therefore with enthusiasm that we start DIAGNODE-2, where we have now screened our first patient. It is important to preserve the endogenous insulin production that remains in newly diagnosed type 1 diabetes patients as even a small amount simplifies life with diabetes, decreases the number of hypoglycemias and leads to fewer long-term complications."

In the report of the open-label pilot trial DIAGNODE-1, where the diabetes vaccine Diamyd® is given directly into the lymph node, results are now presented for all twelve patients that have been followed for 6 months. No serious adverse events have been reported in the trial, and positive effects are seen on the disease progression. At 6 months, the endogenous insulin producing ability is virtually unchanged. On average, insulin production (measured as stimulated C-peptide, AUC) decreased by 1.7% (compared to expected 15%) while at the same time, patients have on average lower (-22%) long-term blood sugar (HbA1c) and use less insulin (-10%) than at the start of trial. Previously reported preliminary 15-month results for six participants show that the endogenous insulin-producing ability has decreased only by 10.8% (compared to expected 35%), and long-term blood sugar and insulin dose have decreased by 31% and 39% respectively. The treatment also provides a desired immunological response.

"DIAGNODE-2, which we have now started, will be very exciting and with participating clinics from Sweden, the Czech Republic and Spain, we will work together for effective patient recruitment," says Ulf Hannelius, CEO of Diamyd Medical.

### About the disease progression in Type 1 diabetes

The results now available should be viewed in perspective as to how the disease progression usually appears in newly diagnosed type 1 diabetes patients. Type 1 diabetes is an autoimmune disease, which means that the beta cells, the cells in the pancreas that form insulin, are broken down by the immune system. The decreasing insulin production leads to higher blood sugar levels and the patient becomes dependent on externally supplied insulin to survive. Based on data from Diamyd Medical's own studies and other published studies in type 1 diabetes, a patient in the same age group as the participants in DIAGNODE-1 loses approximately 15% of his/her own insulin-producing ability (C-peptide AUC) in the first 6 months and 35% by 15 months. Long-term blood sugar and insulin doses usually remain unchanged or slightly elevated at 6 months and by 15 months the negative disease progression continues, with further elevated blood glucose levels requiring higher insulin doses, which in turn increases the risk of both short-term and long-term complications.

### About DIAGNODE-1

DIAGNODE-1 is an open label 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. Twelve patients have been followed for 6 months and out of these six have been followed for 15 months from inclusion.

### About DIAGNODE-2

DIAGNODE-2 is a follow-up on DIAGNODE-1, where preliminary results show a positive clinical progression and desired immunological response as the diabetes vaccine Diamyd® is given directly into the lymph node. DIAGNODE-2 is a double-blind randomized trial encompassing approximately 80 patients from Sweden, the Czech Republic and Spain, aged 12–24 years that have recently been diagnosed with type 1 diabetes. The

patients will be 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 the 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 of 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®, 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 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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