Press release, June 4, 2019

New interim report at 30 months and after extra injection supports long-term effect of intralymphatic Diamyd®

The first seven patients that have now been followed for the entire 30-month period in DIAGNODE-1 continue to show a positive clinical course and are in partial remission. Partial remission in type 1 diabetes is characterized by low external insulin requirement and near to normal long-term blood sugar levels. Three of the seven patients have also received an extra intralymphatic injection of Diamyd® after their 30-month visit. These three patients show an increase in endogenous insulin production between the 30 and 37 month visits. The treatment appears safe and no serious side effects have been reported.

"The results are encouraging", says Johnny Ludvigsson, Professor at Linköping University and Sponsor of the trial. "The clinical course after the booster injection of Diamyd® also looks promising, although conclusions should be drawn carefully as the results are based on only three patients."

In a seventh interim report from the open investigator initiated trial DIAGNODE-1, where the diabetes vaccine Diamyd® is given directly into the lymph node, results are now presented for the first seven patients that have been followed for the entire trial period of 30 months. No serious side effects have been reported in the trial and all patients are still in partial remission. On average, the patients' endogenous insulin production (measured as stimulated C-peptide, AUC) has decreased by 31.8%, while they on average have lower (-25%) long-term blood sugar (HbA1c) and use less insulin (-15%) than at baseline. Overall, this indicates that the clinical course of the disease continues to be positive at 30 months for these first seven patients.

Three of the seven patients are included in an extension of the trial, which entails that they have received a fourth injection, a booster, of Diamyd® (4µg per dose) about 32 months after their inclusion in the trial. These patients have now been followed five months after the fourth injection and will be followed for another 6 months (a total of 11 months after the fourth injection). No serious side effects have been reported in the extension of the trial. On average, the three patients' endogenous insulin production (measured as stimulated C-peptide, AUC) has decreased by 31% from the start of the trial to 30 months and by 19.5% from the start of the trial to 37 months. This means that the endogenous insulin production has increased by approximately 20% between the 30-month visit and the 37-month visit. At the same time, at the 37-month visit, the three patients have on average lower (-39%) long-term blood sugar (HbA1c) and use less insulin (-8%) than at trial start.

About DIAGNODE-1
DIAGNODE-1 is an open clinical pilot trial that comprises a total of twelve patients between 12 and 30 years with newly diagnosed type 1 diabetes, where the diabetes vaccine Diamyd® is injected on three occasions at a monthly interval with a low (4µg) dose directly into the lymph node (intralymphatically). The treatment is combined with oral vitamin D. The trial is designed to evaluate the safety, immunological response and clinical effect of the treatment, with readouts at 6, 15 and 30 month follow-up. The aim of intralympahtic treatment with Diamyd® is to preserve the endogenous insulin production by interrupting the autoimmune process in the body that destroys the insulin-producing cells.

Of the 12 patients who are included in DIAGNODE-1, three adult patients were been asked and agreed to particiatpe in an extension of the trial, which means that they received a fourth injection of Diamyd® about 2.5 years after their inclusion in the trial. The goal of the extension is to evaluate the safety of a fourth injection of Diamyd®, the impact on the immune system and the endogenous insulin production. After the fourth injection, the patients are followed for another 11 months.

DIAGNODE-1 is based on a patent pending intralymphatic treatment method for autoimmune diseases. The purpose of administering directly into the lymph node is to, in a safe and simple manner, increase the effect of antigen-specific immunotherapy, a therapy based on the use of endogenous substances to reprogram the body's

immune system in autoimmune diseases. Antigen-specific intralymphatic immunotherapy (AS-ILIT) differs from the traditional method where antigen is injected under the skin and then transported by immune cells to the lymph nodes. Instead, the injection is made directly into the lymph node, where the immune cells are trained. From there, the cells spread through the body, including to the pancreas where the reprogrammed cells are intended to create a changed response to the autoimmune attack on the insulin-producing beta cells. The fact that intralymphatic administration results in a stronger clinical and immunological effect has previously been shown in the allergy field. Here, several trials have shown that very small amounts of allergen administered directly into the lymph node provide the same effect and safety as significantly higher amounts of allergen injected under the skin for a prolonged period of treatment.

DIAGNODE-1 has paved the way for the double-blind and placebo-controlled trial DIAGNODE-2 that was reported fully recruited in May 2019 with the aim of verifying the results from DIAGNODE-1.

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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