Press release, December 20, 2019

Positive Top-line results from I/II trial with intralymphatic Diamyd®

Diamyd Medical announced today, when all 12 patients have been followed throughout the 30-month period in the open-label trial DIAGNODE-1, that the patients show on average a positive clinical course with a near normal long-term blood sugar and a low need for externally supplied insulin. The three patients who received an extra Diamyd® injection into the lymph node after their 30-month visit showed a maintained own insulin production between the 30- and 43-month visits, as well as lower long-term blood sugar and insulin requirements compared to baseline. Safety looks good and no serious side effects have been reported.

“The results are gratifying and the effect of the extra injection indicates that we have been able to completely maintain the patients own insulin production for a whole year," says Johnny Ludvigsson, Professor at Linköping University and Sponsor of the trial.

In summary, the 12 patients' own insulin production (measured as stimulated C-peptide, AUC) decreased on average over 15 and 30 months by 19% and 42%, respectively. This can be compared with untreated patients in the same age group from previous trials where a decrease of 35-50% is expected already over a 15-month period. On average, the three patients who received a fourth injection of Diamyd® about 2.5 years after the start of the trial reduced their own insulin production by only 29% at 43 months compared to baseline and had unchanged own insulin production between the 30- and 43 month visits.

”That an extra injection can preserve the endogenous insulin production for a whole year is very interesting and and ties in well with the dose dependency we observed in the larger analysis of previous trials with Diamyd® reported last week,” says Ulf Hannelius, CEO of Diamyd Medical. ”It should be emphasized that today's positive results do not take into account genetic subgroups and it will be interesting to see in more in-depth analyzes how intralymphatic administration of Diamyd® relates to these groups.”

Long-term blood sugar (measured as HbA1c) improved, showing an average decrease of 12% at the 30 month visit compared to baseline. This can be compared with untreated patients in the same age group from previous trials where an increase of 18% is expected already over a 15 month period. Patients who received a fourth injection of Diamyd® further improved their blood sugar control, with 37% lower long-term blood sugar at 43 months compared to baseline and no change between the 30- and 43- month visits.

The patients' need for externally administrated insulin increased on average by 31% in 30 months. This can be compared with untreated patients in the same age group from previous trials where an increase of 50% is expected already over a 15 month period. The three patients who received a fourth dose of Diamyd® reduced their need for external insulin by 20% at 43 months compared to baseline. At 30 months from baseline, the patients had reduced their insulin requirements by 5% compared to a 20% reduction at 43 months from baseline. The patients' insulin requirements were consequently lower at 43 months than at 30 months.

10 out of 12 patients were in partial remission at 30 months from baseline (approximately 33 months from diagnosis) and all three patients who received a fourth injection with Diamyd® were in partial remission 43 months from baseline (about 46 months from diagnosis). Partial remission in type 1 diabetes is characterized by a low need for externally supplied insulin and near normal long-term blood sugar.

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 patients have also received oral supplementation with vitamin D during four months. 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 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. Intralymphatic administration has previously been evlauated in the allergy field where it has been shown to result in a stronger clinical and immunological effect. 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 is the first clinical trial to evaluate the administration route in an autoimmune disease with the aim to induce immunological tolerance against an endogenous antigen. 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, two 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. 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 Growth Market 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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