Press release, September 11, 2018

Positive 15-month results with Diamyd® in Type 1 diabetes

When all patients have been followed for 15 months in the diabetes trial DIAGNODE-1, where the diabetes vaccine Diamyd® is given directly into the lymph node, a clearly positive and clinically relevant effect is seen in improving the clinical course and maintaining the endogenous insulin production in newly diagnosed type 1 diabetes.

Diamyd Medical today announced that 15-month results from the DIAGNODE-1 trial show a positive and clinically relevant effect on the three prioritized efficacy endpoints - insulin production, long-term blood sugar level (HbA1c) and external insulin requirement. No serious adverse events have been reported in the trial, and safety is considered very good and comparable to trials where Diamyd® has been administered under the skin. The patients are followed for a total of 30 months.

After three injections directly into the lymph node with the diabetes vaccine Diamyd® combined with oral vitamin D, the patients' average ability to produce insulin, the single most important efficacy endpoint, decreased by 19% over a 15 month period compared to an expected decrease of between 35% and 50% based on untreated type 1 diabetes patients in the same age group from other trials. Compared with untreated patients, the estimated relative effect of the treatment on preserving the patients' own ability to produce insulin at 15 months is 46-62%. Of the trial's total of twelve patients, three have increased their own insulin production over the 15 months they were followed.

The trial participants' long-term blood glucose levels measured as glycated hemoglobin A (HbA1c) improved over the 15 month period. HbA1c decreased by 18% compared with an expected average increase of 15%. Daily insulin doses increased during the 15-month follow-up period, on average by only 6% compared with an expected increased insulin requirement of 50%. Overall, the clinical course is positive and is observed in all ages and for both genders.

No serious adverse events have been observed during the 15 months that trial participants now have been followed and the treatment has been well tolerated by all twelve patients in the trial. The most common adverse reaction was a minor local irritation at the injection site, an adverse reaction observed to the same extent as compared to the trials conducted in more than 1,000 patients where Diamyd® was administered under the skin. Overall, the safety of administering directly into the lymph node is very good and comparable to administering under the skin.

"It is gratifying to note that the previously presented results from the trial persist," says Johnny Ludvigsson, Professor at Linköping University and Sponsor of the trial. "Preserving insulin production is of great importance in reducing complications in diabetes. I hope we are now close to a breakthrough, since a low dose of the diabetes vaccine Diamyd® given directly in the lymph node, in combination with oral vitamin D, seems to provide a good clinical and immunological response and seems to preserve the body's ability to produce insulin".

"With these results from DIAGNODE-1, along with our safety database as well as a treatment that is simple and meets a clear medical need, Diamyd® is a very attractive drug candidate in late clinical development phase with great potential for reaching the market," says Ulf Hannelius, CEO of Diamyd Medical.

About insulin production (C-peptide level) and long-term blood sugar (HbA1c) in Type 1 diabetes
The trial measures the patients' C-peptide levels. C-peptide is a byproduct of the body's own insulin production. The C-peptide level in the blood is measured to determine the size of the body's own production of insulin. After a patient has been diagnosed with type 1 diabetes, the C-peptide level decreases on average by about 50% per year during the first years of diagnosis due to an autoimmune process that destroys the insulin-producing cells in the body. Most patients have no measurable remaining insulin production within a few years after diagnosis. The value of being able to preserve the endogenous insulin production at diagnosis is high since published research shows that even a small remaining insulin production reduces long-term complications by up to 60-80%. The trial also measures the patients' HbA1c levels. HbA1c is also called long-term blood sugar, as it shows the average blood glucose levels over the last 2 to 3 months. HbA1c is formed when hemoglobin reacts with sugar (glucose) in the

blood and is therefore sometimes also called glycated hemoglobin. The higher the sugar content in the blood, the more hemoglobin is transformed into HbA1c. Blood sugar levels that exceed the normal levels for longer periods harm the body's organs and may in the long run lead to very serious complications.

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.

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. With 15-month results from DIAGNODE-1, it can now be seen also in the field of autoimmune diseases, more specifically type 1 diabetes, that small doses of antigen administered directly into the lymph node appear to lead to a significantly stronger clinical effect compared to significantly higher doses administered under the skin.

DIAGNODE-1 has paved the way for the double-blind and placebo-controlled trial DIAGNODE-2 that started in November 2017 with the aim of verifying the results from DIAGNODE-1. Diamyd Medical recently announced that the Swedish Medical Products Agency has approved an extension of the trial from 80 patients to 106 patients. The trial is conducted in Spain, the Czech Republic and Sweden.

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 which in June 2018 was approved by the Swedish Medical Agency for clinical trial. 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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