Press release, October 24, 2016

# Interim report for Diamyd® directly into the lymph node indicates positive clinical course

*Diamyd Medical (Nasdaq Stockholm First North, DMYD B) today announced that the second interim report from DIAGNODE-1, an open clinical pilot study where the diabetes vaccine Diamyd® is administered directly into the lymph node, preliminary shows that the treatment after 15 months appears to be safe and tolerable and that the clinical progression in patients is positive in terms of the body's own capacity to produce insulin, as well as long-term blood sugar and insulin dose. This preliminary evaluation will be presented by Professor Johnny Ludvigsson, principal investigator and sponsor of the study, at the ISPAD diabetes meeting in Valencia, Spain, in October 26 to 29, 2016.*

DIAGNODE-1 is an open label pilot study, comprising a total of fifteen patients between the ages of 12 and 30 with type 1 diabetes, where a low dose of the diabetes vaccine Diamyd® is administered directly into the lymph node in combination with treatment with vitamin D. Preliminary data from six patients are now presented.

"The results, which admittedly are based on few patients, look very promising," says Professor Johnny Ludvigsson at Linköping University, principal investigator and the sponsor of the study, "It is particularly interesting that the beta cell function rather looks to have improved from 6 to 15 months of follow up. My conclusion, which I will present at ISPAD, is that a low dose of the diabetes vaccine Diamyd® given directly into the lymph node, in combination with oral treatment with vitamin D, appears to be tolerable and safe, and provides a strong immune response that could preserve the own ability to produce insulin."

Four patients have been followed for 15 months, and six patients (two new patients) have been followed for 6 months from inclusion in the study, that is, 12 and 3 months after the third injection with diabetes vaccine Diamyd® (4µg per dose) directly into the lymph node. This new, innovative method of administration is in analogy to the development in allergy therapy, where administration of allergen into lymph nodes significantly improved the efficacy. Vitamin D is given in order to down regulate the immune system's inflammatory components and thereby increase the diabetes vaccine's tolerance inducing effect with the aim of preserving the patient's insulin producing capacity.

Professor Johnny Ludvigsson reports that preliminary 15-month data for the first four patients, followed for 15 months, indicates that the safety is good and no serious side effects have been reported. On average, the group decreased its ability to produce insulin (measured by C-peptide AUC) by 6% while fasting C-peptide increased by 34%. Meanwhile, HbA1c (a way to measure long-term blood sugar) and insulin decreased by 22 and 24% respectively.

Earlier this year, Professor Johnny Ludvigsson reported preliminary 6-month data for four patients and now with six-month data for additional two patients, the result for the total of six patients at 6 months is available. The safety looks good and no serious side effects have been reported. On average, the group's own ability to produce insulin (measured by C-peptide AUC) has increased by 3% while fasting C-peptide has decreased by 3%. Meanwhile, HbA1c and insulin dose were reduced by 38 and 28% respectively. This indicates that the previously reported clinical results have not changed when observing six patients compared to the previous four patients.

Immunological markers have been evaluated preliminarily, which suggests that the diabetes vaccine Diamyd® given directly into the lymph node provides a clear and desired re-balancing of the immune system. Here has the so-called Th1 response - which is associated with autoimmunity in type 1 diabetes – been directed towards the so-called Th2 response, which is the desired immunological response with the aim of maintaining the insulin production.

Professor Johnny Ludvigsson will present theses interim results at the "42nd Annual Conference of the International Society for Pediatric and Adolescent Diabetes ISPAD" held on October 26 to 29, 2016 in Valencia, Spain.

**About Diamyd® and combination trials**
Type 1 diabetes is a devastating disease which requires daily treatment with insulin to sustain life. The importance of finding a cure should not be underestimated. The diabetes vaccine Diamyd® has been used in clinical studies with more than 1,000 patients and has shown a good safety profile. In a European Phase III trial Diamyd® showed good clinical effect in several subgroups, and a limited overall 16% efficacy (p=0.10) in preserving endogenous insulin secretion. Subsequent development is focused on combination trials to enhance efficacy. Diamyd® is easy to administer in any clinical setting. The potential annual market is estimated to several billion dollars per year.

Six researcher initiated clinical trials are ongoing combining Diamyd® with various other immunomodulatory compounds; etanercept, ibuprofen, vitamin D and GABA.

- **DIABGAD-1 – COMBINING DIAMYD® WITH IBUPROFEN AND VITAMIN D**
  A placebo-controlled trial, where Diamyd® is being tested in combination with ibuprofen and vitamin D. The trial comprises a total of 64 patients between the ages of 10 and 18, recently diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the combination treatment is to preserve the body's own capacity to produce insulin. The trial runs at nine clinics in Sweden and is led by Professor Johnny Ludvigsson at Linköping University, Sweden. 30 month results from the trial are expected during the first quarter of 2017.

- **DIAGNODE-1 –DIAMYD® IN LYMPH GLANDS IN COMBINATION WITH VITAMIN D**
  An open label trial, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The trial comprises fifteen patients between the ages of 12 and 30 newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the trial is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The trial is led by Professor Johnny Ludvigsson at Linköping University, Sweden. The first patient was included in the trial in February 2015.

- **GABA/DIAMYD® – COMBINING DIAMYD® WITH GABA**
  A placebo-controlled trial, where Diamyd® is being tested in combination with GABA. In accordance with agreement with Jansen Research & Development and JDRF the trial was recently expanded to comprise 95 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes. The trial will continue for a total of 12 months. The aim of the combination treatment is to preserve the body's residual capacity to produce insulin. The trial is led by Dr. Alexandra Martin at the University of Alabama at Birmingham, USA. The first patient was included in the trial in March 2015.

- **EDCR IIa – COMBINING DIAMYD® WITH ETANERCEPT AND VITAMIN D**
  An open label trial, where Diamyd® is combined with etanercept and vitamin D. The trial comprises 20 patients between the ages of 8 and 18 who have been newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the trial is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The trial is led by Professor Johnny Ludvigsson at Linköping University, Sweden. All patients were included in September 2016 and 6 month results are expected during the second quarter of 2017.

- **DiAPREV-IT 1– DIAMYD®**
  A placebo-controlled trial, where Diamyd® is being tested in children at high risk of developing type 1 diabetes, meaning that they have been found to have an ongoing autoimmune process but do not yet have any clinical symptoms of diabetes. A total of 50 participants from the age of four have been enrolled in the trial, which will last for five years. The aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden. Five year results are expected during the first quarter of 2017.

- **DiAPREV-IT 2 – COMBINING DIAMYD® WITH VITAMIN D**
  A placebo-controlled trial, where Diamyd® is being tested in combination with vitamin D in children at high risk of developing type 1 diabetes, meaning that they have been found to have an ongoing

autoimmune process but do not yet have any clinical symptoms of diabetes. A total of 80 participants between the ages of 4 and 18 will be enrolled in the trial, which will last for five years. The aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden. The first patient was included in March 2015.

**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®, an antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Six clinical studies are ongoing with Diamyd®. GABA constitutes alongside with the diabetes vaccine a key asset in Diamyd Medical and the Company uses its GABA in-licensed technology to develop a proprietary GABA drug product. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB (former Cellaviva AB). Diamyd Medical also 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 Stockholm First North under the ticker DMYD B. Remium Nordic AB is the Company's Certified Adviser.

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