Press release, April 1, 2016

Study where Diamyd® is administered directly into lymph nodes approved for expansion and inclusion of children from 12 years of age

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) today announced that DIAGNODE-1, an open-label clinical pilot study in which the diabetes vaccine Diamyd® is administered directly into lymph nodes, has been approved by the Swedish Medical Products Agency and the Ethics Review Board to be expanded from five to nine patients and to include children from 12 years of age.

As previously communicated, Professor Johnny Ludvigsson, principal investigator and sponsor of DIAGNODE-1, has submitted a first preliminary evaluation of data from the first four patients that have been monitored for six months in the study, as an abstract for the diabetes meeting *"51st Annual Meeting of the Scandinavian Society for the Study of Diabetes (SSSD)"* to be held in Reykjavik, Iceland, on April 21-22, 2016. This evaluation preliminarily shows that the treatment appears to be safe and tolerable. Even if the clinical progression in patients shows certain positive data in terms of the body's own capacity to produce insulin, as well as better long-term blood sugar and lower insulin dose (please see press release issued on February 11, 2016), no conclusions are drawn regarding metabolic parameters in these few patients who still may be in the so called honeymoon-phase, often characterized by some regression of the disease.

This data has served as the basis for an application to expand the study from five to nine participants and also to include children and adolescents from 12 years of age. This application has now been approved by the Swedish Medical Products Agency and the Ethics Review Board.

"This is a step forward for this new innovative treatment concept; to be able to study more but also younger patients where the value of immune intervention to save residual insulin secretion is deemed the most important," says Professor Johnny Ludvigsson at Linköping University, principal investigator and sponsor of the study.

The pilot study DIAGNODE-1 is the first study of its kind, where a low dose of Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The concept, for which Diamyd Medical has submitted a patent application, can be compared to the development in allergy therapy, where the administration of allergen into lymph nodes has significantly improved efficacy, while concurrently decreasing the dose. Vitamin D is provided in order to down regulate the immune system's inflammatory components to thereby increase the diabetes vaccine's tolerance inducing effect with the aim of preserving the patient's insulin producing capacity.

DIAGNODE-1 is an open pilot study which after this approval comprises a total of nine patients between the ages of 12 and 30 who have been diagnosed with type 1 diabetes in the past six months. The patients are monitored for 30 months. All participants are given a low dose (4µg) of Diamyd® into a lymph node on three occasions, in combination with intake of vitamin D.

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 due during the first half year 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 nine 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. The trial comprises 75 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes, and 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 Professor Kenneth McCormick 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. The first patient was included in May 2015.

- **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 at the end of 2016.

- **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 autoimmune diabetes through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, an Antigen Based Therapy (ABT) based on the exclusively licensed GAD-molecule. The Company's licensed technologies for GABA and Gliadin have also potential to become key pieces of the puzzle of a future solution to prevent, treat or cure autoimmune diabetes, and also certain inflammatory diseases. At this time six clinical studies are ongoing with Diamyd®. Diamyd Medical is with its holdings of 45% one of the major shareholders in the stem cell company Cellaviva AB. Stem cells can be expected to be used in Personalized Regenerative Medicine (PRM), for example for restoration of

beta cell mass in diabetes patients where the autoimmune component of the disease has been arrested. 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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