Press release, February 11, 2016

Diamyd® administered directly into lymph nodes in young adults with type 1 diabetes – preliminary interim report from DIAGNODE-1

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) today announced that the first six-month interim report from DIAGNODE-1, a clinical pilot study in which the diabetes vaccine Diamyd® is administered directly into lymph nodes, preliminarily shows that the treatment 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 was submitted by Professor Johnny Ludvigsson, principal investigator and sponsor of the study, as an abstract for the SSSD diabetes meeting to be held in Reykjavik in April 2016.

DIAGNODE-1 is a clinical pilot study in young adults with type 1 diabetes in which a low dose of the diabetes vaccine Diamyd® is injected directly into lymph nodes. The treatment is combined with orally administered vitamin D. The initial preliminary data is being presented from four patients that have been monitored for six months since inclusion in the study, meaning five months after the first of three injections of the diabetes vaccine Diamyd® (4µg per dose) was administered directly into the lymph nodes. 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 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.

Professor Johnny Ludvigsson reports that the preliminary data for the four patients, with an average age of 21.8, who have been monitored for six months indicates good safety and no serious side effects have been reported. HbA1c (a way of measuring long-term blood sugar) decreased in all four patients. The insulin dose was reduced in three of the four patients. Over the six-month period the body's own ability to produce insulin (measured as C-peptide, AUC) increased in two of the patients by 32 and 6 percent respectively, and decreased in two of the patients by 29 and 2 percent, respectively. On average, the group increased its ability to produce insulin by 2 percent, while HbA1c and insulin dose decreased by 32 and 25 percent, respectively.

Immunological parameters were also preliminarily evaluated, which showed a clear effect on the immune response compared with other studies in which the diabetes vaccine Diamyd® was injected subcutaneously with a higher dose, instead of a low dose injected directly into the lymph nodes, as in this study.

Professor Johnny Ludvigsson submitted an abstract with these interim results to the *"51st Annual Meeting of the Scandinavian Society for the Study of Diabetes (SSSD)",* in Reykjavik, Iceland*,* which will be held on April 21-22, 2016.

"Although the study is very small and the data that we are now presenting after only six months is preliminary, the results appear positive," says Professor Johnny Ludvigsson at Linköping University, principal investigator and sponsor of the study. "Perhaps we have succeeded in extending the remission phase for these young patients. My conclusion in the abstract that I sent to the SSSD meeting is that a low dose of the diabetes vaccine Diamyd® administered directly into lymph nodes, combined with oral vitamin D treatment, appears not only to be feasible, tolerable and safe, but also appears to create a strong immune response and could preserve the body's own insulin-producing ability. We now intend to expand the study to include additional patients. It is very exciting."

DIAGNODE-1 is an open pilot study comprising a total of five patients between the ages of 18 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 this study, Diamyd® is combined with orally administered vitamin D. A study-expansion application has been submitted to the Swedish Medical Products Agency.

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 five patients between the ages of 18 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. A study-expansion application has been submitted to the Swedish Medical Products Agency.

- **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. A first interim report is planned in the first quarter of 2016.

- **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 39% 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.

For further information, please contact:
Anders Essen-Möller, President and CEO
Phone: +46 70 55 10 679. E-mail: anders.essen-moller@diamyd.com

Diamyd Medical AB (publ)
Kungsgatan 29, SE-111 56 Stockholm, Sweden. Phone: +46 8 661 00 26, Fax: +46 8 661 63 68
E-mail: info@diamyd.com. Reg. no.: 556242-3797. Website: www.diamyd.com.