Press release, October 4, 2016

The Swedish Medical Products Agency approves extension of Diamyd® trial

Diamyd Medical (Nasdaq Stockholm First North, DMYD B) today announced that DIAGNODE-1, an open clinical pilot trial where the diabetes vaccine Diamyd® is tested by given directly into the lymph node, has been approved by the Swedish Medical Products Agency and the Ethics Committee to be expanded from nine to fifteen patients.

The pilot trial DIAGNODE-1 is the first trial 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 the immunomodulating efficacy, while concurrently decreasing the dose. The aim is, in analogy to allergy treatment, to specifically induce immunological tolerance of the patient's insulin-producing beta cells and thereby preserving the patient's insulin producing capacity.

"Intralymphatic administration of Diamyd® has proved safe in the first four patients who have been followed for six months in the trial," says Professor Johnny Ludvigsson at Linköping University, Principal Investigator and sponsor of the trial. "The expansion of the number of patients to 15 is an important step forward in order to evaluate this innovative treatment concept."

DIAGNODE-1 is an open pilot trial that includes patients between the ages of 12 and 30, diagnosed with type 1 diabetes within 6 months. It is an open label trial, meaning that the doctor knows that all patients receive active study drug and thus continuously can evaluate the treatment. Patients will be followed for 30 months. All participants will receive a low dose (4µg) of Diamyd® in the 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 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. At this time 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 Cellaviva AB (changing name to NextCellPharma 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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This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 8.30 CET on October 4, 2016.