Press release, February 3, 2015

First patient enrolled in new study where the Diamyd® diabetes vaccine is administered directly into lymph nodes - DIAGNODE has started

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) informs that the first patient has been enrolled in the DIAGNODE study. In the study a new way to administer the Diamyd® diabetes vaccine is tested, directly into inguinal lymph nodes.

DIAGNODE 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. It is an interesting approach that is now being tried at Linköping University in a small group of adult subjects recently diagnosed with type 1-diabetes.

DIAGNODE is an open label pilot study with five patients between 18 and 30 years of age who have been diagnosed with type 1 diabetes within 6 months. An initial evaluation will be made after 6 months, with a focus on safety and immunological markers, and the patients will thereafter be followed for another 24 months.

All five participants will receive a low dose (4µg) of Diamyd® in the lymph node on three occasions. Diamyd® is in this study combined with a high dose of vitamin D. The 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 in regard of preserving the patient's insulin producing capacity.

"This is a unique study where we hope that the effect of the diabetes vaccine will be enhanced," says Professor Johnny Ludvigsson, Linköping University, Sweden, who is the Principal Investigator of the study. "Giving the diabetes vaccine directly into lymph nodes is an innovative approach that may become of importance both in the treatment of type 1 diabetes as well as other autoimmune diseases."

About the Diamyd® diabetes vaccine
Diamyd® is the world's furthest developed Antigen Based Therapy for preventing, delaying or stopping the autoimmune attack on beta cells in type 1 diabetes and other forms of autoimmune diabetes and thus preserving the body's own ability to produce insulin. The diabetes vaccine Diamyd® is easily administered in any clinical setting and has been used in studies with more than 1000 diabetes patients. In a European Phase III study with children and adolescents recently diagnosed with type 1 diabetes, Diamyd® showed an overall 16% efficacy (p=0.10) versus placebo in preserving endogenous insulin secretion. Ongoing development work is aimed at enhancing the efficacy of the treatment by combining Diamyd® with other agents. Three clinical studies with Diamyd® are ongoing and an additional three are being launched.

- **DIABGAD-1.** A placebo-controlled study, where Diamyd® is being tested in combination with ibuprofen and vitamin D. The study 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 residual capacity to produce insulin. All of the participants have been enrolled in the study and the initial six-month results, focusing on immunological markers, are expected to be presented in the spring of 2015. The study runs at nine clinics in Sweden and is led by Professor Johnny Ludvigsson at Linköping University.

- **DIAPREV-IT.** A placebo-controlled study, where Diamyd® is being tested in children with early stages of 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 study, which will last for five years. The aim of the study is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The study is taking

place in Sweden led by Dr. Helena Elding Larsson at Lund University. Results are expected at the end of 2016.

- **DIAGNODE.** An open label study, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The study will comprise five patients between the ages of 18 and 30 who have been newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the study is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The study is taking place in Sweden led by Professor Johnny Ludvigsson and enrolled the first patient in February 2015.

- **DIAMYD®/GABA.** A placebo-controlled study, where Diamyd® is being tested in combination with GABA. The study will comprise 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 study is taking place in the US led by Professor Kenneth McCormick at the University of Alabama at Birmingham and is in the start-up phase.

- **DIAPREV-IT 2.** A placebo-controlled study, where Diamyd® is being tested in combination with vitamin D in children with early stages 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 study, which will last for five years. The aim of the study is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The study is taking place in Sweden led by Dr. Helena Elding Larsson and is in the start-up phase.

- **EDCR IIa.** An open label study, where Diamyd® is combined with etanercept and vitamin D. The study will comprise 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 study is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The study is taking place in Sweden led by Professor Johnny Ludvigsson and is in the start-up phase.

About Diamyd Medical
Diamyd Medical is dedicated to fighting type 1 diabetes and to working toward a cure for the disease. Its projects include development of combination regimens with the GAD-based Diamyd® diabetes vaccine for arresting the successive destruction of insulin-producing beta cells. Diamyd Medical has an exclusive license to patent rights held by the UCLA related to the GAD molecule. The company has also an exclusive license from UCLA for GABA for the treatment of diabetes and other inflammation-related conditions.

Diamyd Medical is a shareholder in the stem cell company Cellaviva AB, which is establishing a Swedish commercial bank for private family saving of stem cells in umbilical cord blood and other sources of stem cells. Stem cells are expected to be used in Personalized Regenerative Medicine (PRM), for example, to restore beta cell mass in diabetes patients where autoimmunity has been arrested. Diamyd Medical also has an ownership stake in the US medical technology company Companion Medical, Inc., and a minor shareholding and other financial interests in the US gene therapy company Periphagen Holdings, Inc.

Remium Nordic AB is the Company's Certified Adviser.

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