Press release, May 20, 2015

EDCR has started – first patient included in new study combining the diabetes vaccine Diamyd® with etanercept

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) announced today that the first patient has been included in a new study, EDCR, in which the diabetes vaccine Diamyd® will be combined with two other approved agents, the immunosuppressive drug etanercept and vitamin D, with the aim to evaluate the safety of the combination treatment as well as its impact on the immune system in children and adolescents newly diagnosed with type 1 diabetes. With the start of EDCR a total of six clinical studies are now ongoing where alternative approaches with Diamyd® are being tested, either in combination with other agents or by administering the diabetes vaccine at an earlier stage in the disease process, prior to type 1 diabetes diagnosis.

The first patient has now been included in the study EDCR (Etanercept-Diamyd®-Combination-Regimen) which will include 20 children and adolescents between 8 to 18 years of age, newly diagnosed with type 1 diabetes. The aim of the study is to evaluate the combination treatment of Diamyd®, etanercept and vitamin D, from a safety and immunological perspective. Etanercept is a so called TNF-alpha inhibitor used in rheumatic diseases, for example for treating children with juvenile idiopathic arthritis.

"It is an exciting concept to use etanercept to suppress harmful parts of the immune system that are activated in new onset type 1 diabetes and simultaneously, in a discrete antigen-specific fashion, try to induce tolerance with the diabetes vaccine Diamyd®", says Professor Johnny Ludvigsson, Linköping, Sweden, principal investigator and sponsor of the study. "Vitamin D is also an important part of the treatment. The aim of the combination treatment is to stop or delay the autoimmune attack of the pancreatic insulin producing cells."

Diamyd® has shown an overall 16% efficacy (p=0.10) in a European Phase III trial and a good safety profile. Data from clinical trials shows that Diamyd® activates components that down-regulate the immune system as well as components that increase inflammation in type 1 diabetes. By combining the diabetes vaccine with etanercept, the inflammatory response is reduced and the diabetes vaccine's down-regulating, tolerance-inducing effect can have a greater impact. In turn, vitamin D further down-regulates the immune system's inflammatory components in order to strengthen the regulatory effect of the diabetes vaccine. Both vitamin D and etanercept are also considered to have a direct positive effect on the beta cells.

EDCR will be conducted at nine pediatric diabetes clinics throughout Sweden. It is an open label study, meaning that all participants will receive active treatment. The participants will first receive treatment with vitamin D and etanercept for the duration of one month. Two injections with Diamyd® will then be administered one month apart. Treatment with etanercept will continue for a total period of 90 days, and the vitamin D therapy for 15 months. An initial safety evaluation will take place six months after all patients have been included. The participants will subsequently be monitored for another 24 months.

About the diabetes vaccine Diamyd®
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. Diamyd® is considered to be the world's furthest developed Antigen Based Therapy (ABT) for treating the disease. 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 study Diamyd® showed good clinical effect in several subgroups, and a limited overall 16% efficacy (p=0.10) in preserving endogenous insulin secretion. To enhance the overall effect, combination treatments with Diamyd® and other approved agents are being pursued. Diamyd® is easy to administer in any clinical setting. The potential annual market is estimated to several billion dollars.

Six researcher-initiated clinical studies with Diamyd® in different treatment regimens are ongoing:

- **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 in April 2015 the initial six-month results, focusing on immunological markers, were presented. 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 very 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 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 and is 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 comprises 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 and is led by Professor Johnny Ludvigsson. The first patient was included in February 2015.

- **Diamyd®/GABA.** A placebo-controlled study, where Diamyd® is being tested in combination with GABA. The study 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 study is taking place in the US and is led by Professor Kenneth McCormick at the University of Alabama at Birmingham. The first patient was included in March 2015.

- **DiAPREV-IT 2.** A placebo-controlled study, where Diamyd® is being tested in combination with vitamin D in children with very 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 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 and is led by Dr. Helena Elding Larsson. The first patient was included in March 2015.

- **EDCR IIa.** An open label study, where Diamyd® is combined with etanercept and vitamin D. The study 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 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 and is led by Professor Johnny Ludvigsson. The first patient was included in May 2015.

About Diamyd Medical
Diamyd Medical is dedicated to working toward a cure for type 1 diabetes and LADA. The Company's projects include development of combination regimens with the GAD-based diabetes vaccine Diamyd® for arresting the destruction of insulin-producing beta cells. The Company exclusively licenses UCLA-rights to GAD65, the active ingredient in the vaccine, for which the last patent expires in 2032. Additionally, the Company exclusively licenses UCLA patents for using GABA for the treatment of diabetes and other inflammation-related conditions.

Diamyd Medical is one of the major shareholders 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 can be expected to be used in Personalized Regenerative Medicine (PRM), for example, to restore beta cell mass in diabetes patients where autoimmunity has been arrested.

Remium Nordic AB is the Company's Certified Adviser.

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