Press release, November 25, 2014

New concept with the Diamyd® diabetes vaccine approved for testing in children and adolescents with type 1 diabetes

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) informs that the Swedish Medical Products Agency has approved another new researcher-initiated combination study with the Diamyd® diabetes vaccine. In the study, Diamyd® will be combined with two other agents – vitamin D and the immunosuppressive drug etanercept. This is the fourth researcher-initiated clinical trial with the Diamyd® diabetes vaccine to receive regulatory approval this autumn. Two other clinical studies with the diabetes vaccine are already ongoing.

This is the first time that this combination of agents is tested against the complex autoimmune process that causes type 1 diabetes. The treatment aims to maintain the remaining ability of patients to produce their own insulin by halting the immune system's attack on the insulin-producing beta cells. Maintaining the body's endogenous insulin-producing capacity, in turn, leads to better blood glucose control and reduces the risk of both acute and long-term complications from type 1 diabetes.

"Diamyd® is currently at the forefront of development in Antigen-Based Therapy regarding efforts to cure type 1 diabetes and we are committed to being first to market with a combination therapy," says Anders Essen-Möller, Chairman of the Board of Diamyd Medical.

The newly approved study, EDCR IIa (Etanercept-Diamyd-Combination-Regimen), comprises 20 children and adolescents between 8 and 18 years who have recently been diagnosed with type 1 diabetes. It is an open-label trial, which means that all participants will receive active combination therapy. The aim of the trial is to evaluate the combined therapy of vitamin D, etanercept and the Diamyd® diabetes vaccine from a safety perspective, and how the immune system is affected. Etanercept is a TNF-alpha inhibitor used in rheumatic diseases and is approved in Sweden, for example, for treating children with juvenile idiopathic arthritis (JIA).

"The idea is that etanercept will suppress those parts of the immune system that are activated during the autoimmune process in new onset type 1 diabetes," says Professor Johnny Ludvigsson at Linköping University, principal investigator and sponsor of the study. "The aim of this and the vitamin D therapy is to improve the efficacy of the diabetes vaccine and thus maintain the body's residual capacity to make insulin. This is not unlike the original rationale for Diamyd® as a single agent treatment, but now expanded with important modifications based on the knowledge gained from previous clinical trials of the diabetes vaccine."

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 efficacy of the diabetes vaccine. Both vitamin D and etanercept are also considered to have a direct positive effect on the beta cells.

The new trial will be conducted at several pediatric diabetes clinics throughout Sweden. 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 evaluation will take place six months after all patients have been included. The participants will subsequently be monitored for another 24 months.

About the Diamyd® diabetes vaccine
Diamyd® is an Antigen Based Therapy (ABT) that is being developed with the objective of preventing, delaying or stopping the autoimmune attack on beta cells in type 1 diabetes and other forms of autoimmune diabetes and

thus preserve the body's own ability to produce insulin. The active substance in the Diamyd® diabetes vaccine is glutamic acid decarboxylase isoform 65kDa (GAD). GAD is one of the most important targets when the immune system attacks the beta cells in autoimmune diabetes. Accordingly, GAD is an autoantigen. Treatment using Diamyd® is intended to stop the autoimmune attack against the beta cells by inducing tolerance to GAD. Diamyd® has been used in clinical trials including more than one thousand patients with a good safety profile. Diamyd® is easy to administer in any clinical setting.

Ongoing development work is aimed at enhancing the efficacy of the treatment and providing the right conditions for the diabetes vaccine to exert an effect by combining Diamyd® with other agents and to treat earlier in the disease process. New approaches are being evaluated in several clinical studies together with different teams of researchers. Today, two researcher-initiated clinical studies with Diamyd® are in progress and an additional four have recently received regulatory approval and are being launched. These studies are being financed through research grants, while Diamyd Medical is providing the study drugs and covers certain other costs, and has participated in the design of the studies and is also able to utilize the findings of the studies.

- **DIABGAD-1.** A blind, 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 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 test whether the combination treatment can 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 beginning of 2015. The study is taking place in Sweden led by Professor Johnny Ludvigsson at Linköping University.

- **DIAPREV-IT.** A blind, 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. All of the participants have been enrolled in the study and results are expected at the end of 2016.

- **DIAMYD®/GABA.** A blind, placebo-controlled study, where Diamyd® is being tested in combination with GABA. The study will comprise a total of 75 patients between the ages of 4 and 18 who have been newly diagnosed with type 1 diabetes, and will continue for a total of 12 months. The aim of the study is to test whether the combination treatment can 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 blind, 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.

- **DIAGNODE.** An open label study, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The study will comprise a total of 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 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 a total of 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 type 1 diabetes
Type 1 diabetes is an autoimmune disease where the immune system attacks the patients' own insulin-producing beta cells. By analyzing markers in the blood, it is possible to identify persons in whom this autoimmune process is ongoing, although has not yet caused clinical symptoms of diabetes. When clinical symptoms present, patients must be treated daily, for the rest of their lives, with insulin to sustain life. Finding a cure is of major importance for the world's healthcare systems and the well-being of patients. The annual market for an easy-to-use, successful therapeutic is estimated at several billions of dollars.

About Diamyd Medical
Diamyd Medical is dedicated to fighting type 1 diabetes and to working toward a cure for the disease. Diamyd Medical's projects include development of combination regimens with the GAD-based diabetes vaccine Diamyd® for arresting the successive destruction of insulin-producing beta cells. Diamyd Medical licenses exclusive intellectual rights for the GAD molecule from the University of California. The company also has an exclusive license from the University of California for therapeutic use of GABA for the treatment of diabetes and other inflammation-related conditions, including metabolic syndrome and rheumatoid arthritis.

Diamyd Medical owns 46% of 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 a 10% shareholding in the medical technology company Companion Medical, Inc., based in San Diego, in the US, 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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