Press release, January 7, 2015

Diamyd Medical's patent protection extended to 2032 in pivotal decision

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) informs that The Regents of the University of California on behalf of its Los Angeles Campus (UCLA) has been granted another key US patent for its GAD65 technology on which the Diamyd® diabetes vaccine is based. The term of the new patent runs into 2032, which is approximately 10 years longer than current US patents. Diamyd Medical is the exclusive licensee to the new patent.

The Diamyd® diabetes vaccine is an Antigen Based Therapy (ABT) under development for the treatment and prevention of autoimmune diabetes. The active substance is glutamic acid decarboxylase isoform 65 kDa (GAD65). Diamyd® has been used in trials totaling more than one thousand patients with an excellent safety profile. Diamyd® has shown an overall 16% efficacy (p=0.10) versus placebo in preserving endogenous insulin secretion in a Phase III trial with children and adolescents recently diagnosed with type 1 diabetes. The diabetes vaccine is currently being further developed as an ABT in six approved clinical trials in combination with other therapeutic agents. Diamyd® is easy to administer in any clinical setting.

The new patent was issued after a pivotal decision by the United States Patent and Trademark Office on January 6, 2015. The patent application was filed before June 8, 1995, when the patent rules included that the patent term is 17 years from issuance. Expiration date will therefore be January 6, 2032. The new patent is of central importance to Diamyd Medical's GAD65 patent estate as it protects the use of GAD65 for treatment of autoimmune disease including diabetes.

"Long development times often result in short remaining patent protection once a product reaches the market, and this is an important parameter when pharmaceutical companies look for products that may pay off long term," says Anders Essen-Möller, Chairman of the Board of Diamyd Medical. "In our case, with more than 15 years of development, including rather large studies, Diamyd® has shown a certain effect and a good safety profile. That this development project now has been granted renewed patent protection, as if Diamyd® was a product for which development was just about to begin, is unique and will result in an increased interest."

Over the last years, it has become apparent that the autoimmune process that causes type 1 diabetes must be attacked from several angles simultaneously through the combination of at least two drugs in which an Antigen Based Therapy (ABT) is considered a critical component. Diamyd® is the furthest developed ABT for type 1 diabetes worldwide.

In type 1 diabetes 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 clinical symptoms of diabetes have not yet been established. 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 for the well-being of patients. The annual market for an easy-to-use therapeutic is estimated at several billion dollars.

About the Diamyd® diabetes vaccine
Diamyd® 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. Ongoing development work is aimed at enhancing the efficacy of the treatment 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 ongoing and an additional four 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 beginning 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.

- **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.

- **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 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.

For further information, please contact:
Anders Essen-Möller, Chairman, 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.