Press release, March 4, 2015

First patient included in US Diamyd® and GABA diabetes study

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) informs that the first patient has been randomized and dosed in a pioneering study combining the diabetes vaccine Diamyd® with GABA in children with new onset type 1 diabetes. The aim of the combination therapy is to preserve the body's residual capacity to produce insulin.

The first patient has now received the first injection of either the diabetes vaccine Diamyd® or placebo in the recently FDA approved researcher-initiated GABA and Diamyd® combination study. The study is led by Dr Kenneth McCormick, Professor of Pediatrics at the University of Alabama at Birmingham and Director of the UAB Division of Pediatric Endocrinology at Children's of Alabama, USA.

"With over 2,000 type 1 diabetes patients, the Pediatric Diabetes Clinic at Children's of Alabama in Birmingham, Alabama, is at the forefront of medicine", says Professor McCormick. "Years of planning have gone into this groundbreaking study using the diabetes vaccine Diamyd® and oral GABA to preserve or replenish insulin-secreting beta cells. We are truly excited to initiate this innovative therapy in children who are newly diagnosed with type 1 diabetes."

The GABA and Diamyd® combination study is a three-arm, double-blind, placebo-controlled trial and will enroll a total of 75 newly diagnosed type 1 diabetes children and adolescents between 4 and 18 years of age. Patients will be assigned to one of three treatment groups to receive either: a) two injections of Diamyd® plus GABA for 12 months; b) GABA only; or c) placebo. Patients will be followed for a total of 12 months, after which the effect on preserving endogenous insulin production will be analyzed.

Diamyd Medical has in-licensed exclusive rights for therapeutic use of GABA (gamma-aminobutyric acid) for the treatment of diabetes and other inflammation-related conditions. Combination therapy with GABA and GAD65, which is the active substance in the Antigen Based Therapy Diamyd®, has been shown to act synergistically and prolong the survival of transplanted insulin producing beta cells in type 1 diabetes animal models (Tian et al. PLoS One 2011; 6(9):e25337).

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 type 1 diabetes presents with clinical symptoms, patients must be treated daily, for the rest of their lives, with insulin to sustain life. The importance of finding a cure is high for the world's health care systems and the wellbeing of patients. The annual market for an easy to use, successful therapeutic is estimated to several billion dollars.

About the diabetes vaccine Diamyd®
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 1,000 diabetes patients and has shown a good safety profile. 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. Four clinical studies with Diamyd® are now ongoing and an additional two 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 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 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. 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 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 Children's of Alabama
Since 1911, Children's of Alabama has provided specialized medical care for ill and injured children, offering inpatient and outpatient services throughout central Alabama. Ranked among the best pediatric medical centers in the nation by US News & World Report, Children's provided care for youngsters from every county in Alabama, 42 other states and 10 foreign countries last year, representing more than 653,000 outpatient visits and nearly 14,000 inpatient admissions. With more than 2 million square feet, Children's is the third largest pediatric medical facility in the USA. More information is available at www.childrensal.org.

About University of Alabama at Birmingham
Known for its innovative and interdisciplinary approach to education at both the graduate and undergraduate levels, the University of Alabama at Birmingham is the state of Alabama's largest employer and an internationally renowned research university and academic health center; its professional schools and specialty patient-care programs are consistently ranked among the nation's top 50. Find more information at www.uab.edu and www.uabmedicine.org.

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 diabetes vaccine Diamyd® 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, President and CEO, 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.