Press release, April 13, 2015

Immunological markers affected after six months in a first combination study with the diabetes vaccine Diamyd®

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) announced today that a first evaluation, after six months, of immunological markers in DIABGAD has been performed. DIABGAD is one of five ongoing clinical studies with the diabetes vaccine Diamyd®. Both anti-inflammatory and inflammatory immunological markers are affected by the Diamyd® treatment. The safety profile is good, with regards to the combination of Diamyd® with vitamin D and ibuprofen, as well as the combination of single or double doses of Diamyd® with vitamin D. Metabolic results, such as the treatment's effect on the ability to produce insulin, are expected to be ready for presentation by end of 2015 when all patients have completed their 15-month follow-up.

The immunological results after six months are presented at an international diabetes congress, IDS, held in Munich on April 12-16, 2015.

"This far we can see that vitamin D concentrations in serum are elevated, GAD antibodies are induced as expected, and that the treatment has GAD-specific effects both with regards to anti-inflammatory and inflammatory cytokine responses," says Professor Johnny Ludvigsson, Linköping, Sweden, principal investigator and sponsor of the study. "It will be exciting to see how this can affect parameters such as endogenous insulin producing capacity at 15 months."

The study DIABGAD, which is the first study of its kind, combines the diabetes vaccine Diamyd® with relatively high daily doses of vitamin D and the anti-inflammatory drug ibuprofen. The aim with the combination treatment is, after 15 months, to see a difference between treated patients and placebo with regards to the body's own ability to produce insulin in children and adolescents, newly diagnosed with type 1 diabetes. The patients will be followed for a total period of 30 months.

"These immunological results, six months into the study, should be seen as partial results of the complete study DIABGAD," says Anders Essen-Möller, President and CEO of Diamyd Medical. "We can also use them to compare the immunological influence of different treatment concepts in other studies with Diamyd®. To attack the disease process from several angles simultaneously by combining Diamyd® with other drugs, or by administering Diamyd® directly into lymph nodes or earlier in the disease process, are alternative approaches tested in five different clinical studies today. From a safety perspective we consider the six-month results good. Even if we cannot draw any conclusion from these immunological results with regards to a clinically relevant effect on metabolic diabetes associated parameters, we have good hope, as previously informed, that the 15-month results by the end of this year will show positive metabolic results."

DIABGAD is a double-blind, randomized and placebo-controlled Phase II study in which 64 children and adolescents, 10-18 years of age and newly diagnosed with type 1 diabetes, have been treated with either the diabetes vaccine Diamyd® or placebo in combination with ibuprofen and vitamin D. The patients are randomly assigned to four treatment groups: a) Diamyd® in combination with ibuprofen and vitamin D, b) Diamyd® in combination with vitamin D, c) Diamyd® in double dose in combination with vitamin D; d) Placebo (inactive substance).

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.

Five researcher-initiated clinical studies with Diamyd® are ongoing and one additional is 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 presented in April 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. 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 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 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.

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.