



Press release, February 2, 2015

New analyses by international diabetes expertise provides strong support for the Diamyd® diabetes vaccine

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) informs that internationally leading researchers within the field of type 1 diabetes, independently of Diamyd Medical, has reanalyzed results from previous clinical studies with the Diamyd® diabetes vaccine using alternative statistical methods, termed Bayesian analysis. In an abstract submitted to a scientific meeting the authors conclude that the GAD-based diabetes vaccine Diamyd®, with very high probability preserves patients' insulin producing capacity and that the continued development should aim to increase the efficacy.

The authors that include several of the most respected researchers within type 1 diabetes, Craig Beam, Colleen MacCallum, Kevan Herold, Diane Wherrett, Jerry Palmer, Johnny Ludvigsson and the Type 1 Diabetes TrialNet Study Group, have compiled the abstract entitled "GAD65 Vaccination Probably Reduces Insulin Loss in Recent Onset Type 1 Diabetes".

"We are pleased to see that reevaluation of the recent studies with the GAD-vaccine using Bayesian methods shows that the GAD-vaccine likely has a beta cell preserving effect in new onset type 1-diabetes patients," says Professor Craig Beam, Division Director, Epidemiology and Biostatistics, at Western Michigan University Homer Stryker MD School of Medicine in Kalamazoo, USA. "Bayesian statistics is an emerging way of assessing probabilities and has now permeated all the major areas of medical statistics, including clinical trials, epidemiology, meta-analyses and more."

"It is very encouraging that several prominent international researchers now support the notion that antigen specific treatment with Diamyd® with very high probability has an effect in type 1 diabetes," says Professor Johnny Ludvigsson, Linköping University, Sweden, who has been the Principal Investigator for several of the previous studies. "We continue to study if combinations with other drugs can strengthen the effect of GAD treatment in several new clinical studies."

In short the authors state the following in the abstract:

The GAD65 vaccine has been studied in several randomized controlled trials (1-3) as an effective intervention for insulin preservation in Type 1-diabetes. Reevaluation of the studies using Bayesian methods resulted for the initial study (1), that the probability of a reduction in insulin loss (measured by stimulated C-peptide) from GAD to be 99.38%. Bayesian analysis of the first follow-up study (2) lowered the probability of reduced insulin loss from GAD to 68.82%. The second follow-up study (3) increased the probability of insulin-loss reduction from GAD to over 97.00%. In sum, evidence from published randomized controlled trials consistently suggest that the GAD vaccine probably acts to lessen the loss of insulin production in the new onset Type 1 diabetic patient. It is concluded that the entirety of published evidence points toward continued investigation of the GAD vaccine and, specifically, into ways to increase its effectiveness.

1. Ludvigsson J, Faresjo M, Hjorth M, et al. GAD treatment and insulin secretion in recent-onset type 1 diabetes. *The New England journal of medicine*. Oct 30 2008;359(18):1909-1920.
2. Wherrett DK, Bundy B, Becker DJ, et al. Antigen-based therapy with glutamic acid decarboxylase (GAD) vaccine in patients with recent-onset type 1 diabetes: a randomised double-blind trial. *Lancet*. Jul 23 2011;378(9788):319-327.
3. Ludvigsson J, Krisky D, Casas R, et al. GAD65 antigen therapy in recently diagnosed type 1 diabetes mellitus. *The New England journal of medicine*. Feb 2 2012;366(5):433-442.

About the Diamyd® diabetes vaccine

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 1000 diabetes patients. 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. Two 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 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 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.

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