Press release, November 11, 2014

Pioneering study combining the diabetes vaccine Diamyd® with GABA in children with type 1 diabetes approved by the US FDA

Diamyd Medical (Nasdaq Stockholm First North, Ticker: DMYD B) informs that an investigator initiated study combining the diabetes vaccine Diamyd® and GABA in children with new onset type 1 diabetes has been approved by the US Food and Drug Administration. Diamyd Medical and University of Alabama at Birmingham has entered a Clinical Trial Agreement regarding the study, which will be conducted at Children's of Alabama in Birmingham, USA. The combination has shown promising results in preclinical studies.

Principal Investigator for the new GABA and Diamyd® combination study is Kenneth McCormick, MD, Professor of Pediatrics at University of Alabama at Birmingham.

"We envisage that administering GABA to those with new onset type 1 diabetes may preserve residual insulin production, suppress glucagon release, and decrease inflammation in and around the pancreas," says Dr. McCormick. "Combining this with Diamyd®, which aims to specifically halt the autoimmune attack may synergistically help save endogenous insulin production, improve glycemic control and decrease the risk of hypoglycemia and long-term complications."

The clinical 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 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).

The Diamyd® diabetes vaccine 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. The aim of combing treatment with Diamyd® and GABA is to test if this effect can be enhanced.

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 Diamyd Medical
Diamyd Medical is dedicated to fight type 1 diabetes and to work towards a cure for the disease. Diamyd Medical's current projects include development of combination regimens for arresting the successive destruction of insulin producing beta cells using the Company's GAD65-based diabetes vaccine Diamyd®, such as Diamyd® + Vitamin D with or without an anti-inflammatory compound; and Diamyd® combined with GABA, for which

Diamyd Medical licenses exclusive intellectual rights from the University of California in Los Angeles (UCLA). Diamyd Medical has further acquired 46% of the stem cell company Cellaviva AB that 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 required for 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, Chairman Diamyd Medical AB
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.