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Diamyd-licensed technology cures diabetes in pre-clinical model

Diamyd Medical (NASDAQ OMX First North, Ticker: DMYD B) informs that researchers at UCLA have confirmed earlier findings that combinations of GABA and Antigen Based Therapy (ABT) works synergistically as a treatment in the NOD mouse model of type 1 diabetes. Diamyd Medical is the exclusive licensee for the commercialization of UCLA's GABA technology for metabolic diseases including in diabetes.

A recent paper (Tian, Dang, Kaufman, et al. Diabetes 2014;63:3128–3134) reports that newly diabetic NOD mice have successfully been treated and some even cured using a combination regimen consisting of GABA and Antigen Based Therapy (ABT). The ABT used in the study was pro-insulin formulated in alum, while similar results were obtained with GAD65 in alum as the ABT in a previous paper using an islet transplantation NOD model (Tian, Dang, Kaufman. PLoS One 2011;6:e25337). GAD65 is the active substance in Diamyd[®], the Company's ABT which is currently being tested in children for the treatment and prevention of type 1 diabetes.

The findings provide proof-of-principle that combining ABT with an anti-inflammatory agent, such as GABA, can effectively restore normoglycemia in newly diabetic mice. The therapy is reported to preserve insulin producing cells as well as to promote their replication. It is concluded in the new paper, that the use of GABA in combination with an ABT may hold promise for type 1 diabetes intervention in humans.

A group at the University of Alabama, Birmingham, in collaboration with Diamyd Medical, is planning a randomized, double-blind, placebo-controlled clinical study with the combination GABA and Diamyd[®] as ABT in patients with new onset type 1 diabetes. Discussions with the FDA regarding the study design are ongoing.

“Diamyd[®] is to our knowledge the world's furthest developed ABT for type 1 diabetes,” says Anders Essen-Möller, Chairman of Diamyd Medical. “ABT is considered an essential component of a future successful combination therapy for this disease. Several combinations are being studied or are in the pipeline to be studied and there is a good chance that Diamyd[®] will be the first ABT to cross the winning line.”

Type 1 diabetes is an autoimmune form of diabetes where the immune system attacks the patients' own insulin producing beta cells. For these patients, daily treatment with insulin is mandatory 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 GABA

GABA stands for gamma amino butyric acid and is produced in the body as glutamate is decarboxylated by the GAD enzyme. GABA is an important suppressive and “calming” neurotransmitter. Recent pre-clinical findings support the use of GABA as a synergistic component for treatment of autoimmune diabetes and beta cell regeneration as well as for controlling

inflammation, such as in rheumatoid arthritis, metabolic syndrome and type 2 diabetes. Diamyd Medical has licensed Intellectual Proprietary Rights from UCLA for these applications.

About Diamyd®

Diamyd® is a therapeutic under development for the treatment and prevention of autoimmune diabetes. 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) in a European Phase III trial and is currently being further developed in combination regimens with other therapeutic compounds. Diamyd® is easy to administer in any clinical setting.

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 for example Diamyd® + Vitamin D with or without an anti-inflammatory compound; and Diamyd® + 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 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.