



Press release, September 12, 2014

New method to give Diamyd® will be tested in adults with type 1 diabetes

Diamyd Medical (NASDAQ OMX First North, Ticker: DMYD B) informs that a new way to give Diamyd® will be tested in a clinical study with five adults newly diagnosed with type 1 diabetes. The investigator initiated study has been approved by the Swedish MPA.

In analogy to the development in allergy therapy, where the administration of allergen into lymph nodes has significantly improved the efficacy, Diamyd® will in this study be administered directly into lymph nodes in combination with treatment with vitamin D.

“This is an innovative approach that may become important both for the treatment of type 1 diabetes as well as other autoimmune diseases,” says Professor Johnny Ludvigsson at Linköping University, principal investigator of the study. “We have previously shown that Diamyd® has some effect in terms of preservation of the insulin producing beta cells and now we are trying different ways to enhance this effect. Direct intralymphatic administration is one such way. Combination regimens with potentially effective molecules that fight the disease from other angles is another way. Just as in cancer therapy, different combination regimens must be tested to arrive at a cure of autoimmune diabetes.”

Diamyd® is an Antigen Based Therapy (ABT) developed for the treatment and prevention of type 1 diabetes. The active ingredient is the autoantigen GAD. Diamyd® has shown an overall 16% efficacy ($p = 0.10$) in a European Phase III study and is intended to be included as a component in combination therapies for the disease.

“Diamyd® is today the furthest developed ABT for the treatment and prevention of type 1 diabetes,” says Anders Essen-Möller, Chairman of Diamyd Medical. “We have identified several approved drugs that we believe act synergistically with our ABT. A clinical study with Diamyd® in combination with ibuprofen and vitamin D is ongoing and several others are being prepared.”

The new study, DIAGNODE, is an open label pilot study with five patients between 18 and 30 years of age who have been diagnosed with type 1 diabetes within 6 months. An initial evaluation will be made after 6 months, with a focus on safety and immunological markers, and the patients will thereafter be followed for another 24 months.

All five participants will receive a low dose (4µg) of Diamyd® in the lymph node on three occasions. Diamyd® is in this study combined with a high dose of vitamin D. The vitamin D is provided in order to down regulate the immune system’s inflammatory components to thereby increase the ABT’s tolerance inducing effect in regard of preserving the patient’s insulin producing capacity.

About type 1 diabetes

Type 1 diabetes is an autoimmune disease 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 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=0.1) versus placebo regarding preservation of the patients' endogenous insulin secretion 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 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.

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