



Press release, September 17, 2019

Preliminary results from GABA/Diamyd® trial

Preliminary results from the US investigator initiated GABA/Diamyd® trial were presented today at the annual meeting of the EASD in Barcelona, Spain. Initial analyses indicate that GABA alone or in combination with two 20 µg Diamyd® injections under the skin (in contrast to three injections into a lymphnode as in the ongoing DIAGNODE trials) to recent onset type 1 diabetes patients does not significantly affect insulin production, blood glucose values or insulin dose compared to placebo. A potential positive effect of GABA on lowering glucagon levels was observed. No serious side effects were reported. In-depth metabolic analyses and immunological results are expected to follow.

Out of 101 patients that were enrolled in the trial, 97 patients were randomized and started the treatment and 91 are included in the preliminary analysis. There were no significant differences in baseline parameters between the GABA (n=39), GABA/Diamyd® (n=22) and placebo (n=30) groups, indicating that randomization was successful. Preliminary analyses indicate no significant differences in the change from baseline to 12 months in endogenous insulin production, blood glucose or insulin dose between the treatment arms. Importantly, a strong response was observed in the placebo arm, where two patients showed insulin-independence and two patients very low insulin requirements at 12 months. A decrease over time in compliance to GABA treatment (and GABA placebo) was also observed.

A positive trend for lower glucagon levels during fasting and after a liquid meal was observed in the two active treatment arms versus placebo. Dysfunctional glucagon secretion is a common hallmark and a potential therapeutic target for type 1 diabetes and long-standing type 2 diabetes. The hormone glucagon is secreted by pancreatic alpha cells and stimulates the release of glucose to the blood stream.

“We are surprised by the placebo response that we observed in a few patients,” says Professor Kenneth McCormick at University of Alabama at Birmingham, Principal Investigator and Sponsor of the trial. “In-depth analyses are required to better understand this as well as the potentially positive finding regarding decreased glucagon levels in GABA treated patients. I would like to thank all the patients as well as the clinical staff and collaborators without whom it would have been impossible to conduct this trial at one single clinic”.

“These results are in line with previous, smaller combination trials where Diamyd® has been administered under the skin,” says Ulf Hannelius, CEO of Diamyd Medical. “We remain focused on intralymphatic administration of Diamyd® and take note of the surprising observation regarding a decrease in glucagon levels that seems to be associated with GABA supplementation. Additional analyses of this trial and the ongoing ReGenerate-1 trial with our own formulation of GABA, Remygen®, will provide additional insights into this potential finding”.

About the GABA/Diamyd® trial

GABA/Diamyd® is a three-arm, double-blind and placebo-controlled trial including a total of 101 children and adolescents between 4 and 18 years, recently diagnosed with type 1 diabetes. The patients have been randomly assigned to one of three treatment groups: a) two injections of Diamyd® (administered subcutaneously) in combination with daily oral treatment with GABA, b) GABA only, or c) placebo. Patients have been followed for 12 months after which the effect on the preservation of the endogenous insulin production has been analyzed. The trial has been conducted in the United States and led by Professor Kenneth McCormick at University of Alabama at Birmingham, Principal Investigator and Sponsor of the trial. Dr. McCormick treats patients at Children’s Hospital of Alabama.

About Diamyd Medical

Diamyd Medical develops the diabetes vaccine Diamyd®, as an antigen-specific immunotherapy for the preservation of endogenous insulin production. Diamyd® has demonstrated good safety in trials encompassing more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company’s own European

Phase IIb trial DIAGNODE-2 where the diabetes vaccine is administered directly into a lymph node, two investigator initiated clinical trials are ongoing with Diamyd[®]. Diamyd Medical also develops the GABA-based investigational drug Remygen[®] for regeneration of endogenous insulin production. An investigator-initiated Remygen[®] trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB and has holdings in the medtech company Companion Medical, Inc., San Diego, USA.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser; phone: +46 8-528 00 399, e-mail: info@fnca.se.

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