



Press release, July 4, 2018

The GABA/Diamyd® trial in the US now fully recruited

The placebo-controlled trial evaluating GABA in combination with Diamyd®, conducted at the University of Alabama at Birmingham in the U.S, is now fully recruited and has included 101 patients. Of these, 56 patients have already completed the entire trial. No serious side effects have been reported.

"The trial in Alabama is important in our commitment to GABA-based drugs in diabetes," says Ulf Hannelius, CEO of Diamyd Medical. "It gives us vital insights both regarding GABA's therapeutic effects alone in type 1 diabetes as well as in combination with Diamyd®. Along with Remygen® and ongoing intralymphatic trials with Diamyd®, this trial paves the way for new transformative treatments."

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 are randomly assigned to one of three treatment groups: a) two subcutaneous injections (under the skin) with Diamyd® in combination with oral treatment with GABA, b) GABA only, or c) placebo. Patients are followed for 12 months after which the effect on the preservation of the endogenous insulin production will be analyzed. The trial is conducted in the United States and led by Professor Kenneth McCormick who is principal investigator and sponsor of the trial at the University of Alabama at Birmingham and Children's of Alabama.

"This single-center GABA/Diamyd® trial in pediatric patients with type 1 diabetes has exceeded enrollment expectations while accomplishing to recruit the patients within 5 weeks of diagnosis," says Professor McCormick.

Results from the trial are expected to be presented in the final quarter of 2019.

About Diamyd Medical

Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, with its patent-pending technology for antigen-specific intralymphatic immunotherapy (AS-ILIT) based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in studies with more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company's own European Phase II trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymph node, there are four investigator initiated clinical trials ongoing with Diamyd®. Diamyd Medical also develops Remygen®, an oral GABA-based study drug which in June 2018 was approved for a clinical trial by the Swedish MPA. An investigator- initiated placebo-controlled trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is ongoing at the University of Alabama at Birmingham. Exclusive licenses for GABA and positive allosteric modulators of GABA receptors for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine Diamyd® and Remygen® key assets. Diamyd Medical is also 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 and in the gene therapy company Periphagen, Inc., Pittsburgh, USA.

Diamyd Medical's B-share is traded on Nasdaq First North under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser

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