



Press release, May 29, 2019

The Swedish Medical Products Agency approves new treatment arm with Remygen® and Alprazolam in Phase I/II trial ReGenerate-1

The approval by the Swedish MPA entails that ReGenerate-1, with Diamyd Medical's GABA-based investigational drug Remygen®, will be expanded from the original two treatment arms encompassing Remygen® administration, with a third treatment arm in which 12 patients receive Remygen® in combination with the GABA receptor modulator Alprazolam.

“The Agency's positive decision is very gratifying and gives us as the first group in the world the opportunity to evaluate this combination in a clinical trial,” says Per-Ola Carlsson, Professor at Uppsala University and Uppsala University Hospital, Sponsor of the trial.

“GABA in combination with Alprazolam is very interesting and research shows great potential to stimulate an increase in the endogenous insulin production,” says Ulf Hannelius, CEO of Diamyd Medical. “Having the opportunity to evaluate this in a clinical setting is another step forward in our commitment to GABA-based treatments in diabetes.”

Preclinical studies have shown that GABA, the active substance in Remygen®, has the potential to regenerate insulin-producing cells in type 1 diabetes. It has also been shown that GABA receptor modulating agents such as Alprazolam may increase the positive effect of GABA on beta cell function. As previously announced, (<https://www.diamyd.com/docs/pressClips.aspx?ClipID=2708766>), Diamyd Medical licenses patent applications for this combination therapy and the Swedish Medical Products Agency's decision now makes possible the first clinical evaluation of that combination.

About ReGenerate-1

ReGenerate-1 is an open, investigator initiated clinical trial involving a total of about 36 patients aged 18-50 who have had type 1 diabetes for more than five years and have low to non-residual insulin production. The trial is conducted at the Uppsala University Hospital with Professor Per-Ola Carlsson as principal investigator. The trial consists of two parts; an initial safety and dose escalation section comprising six patients, and the main trial, which comprises 36 patients who will be followed up to nine months depending on the dose group to which they belong. The main purpose is to evaluate the safety of Remygen®, Diamyd Medical's own formulation of GABA, and the combination of Remygen® and Alprazolam. The trial will also examine whether Remygen® alone and in combination with Alprazolam can restore its own insulin-producing ability, which in the long run would mean that the patients can regain or increase their own insulin production.

About type 1 diabetes

Type 1 diabetes is an autoimmune disease which means that the beta cells, the cells of the pancreas that produce insulin, are broken down by the immune system. Type 1 diabetes lacks cure and is associated with serious short and long term complications such as acute blood sugar (hypoglycaemia), cardiovascular problems, kidney damage and nerve damage leading to great human suffering and high cost to society.

When the disease is diagnosed, the patient has only about 20% left of his own insulin production, an acute life-threatening condition. Life-sustaining insulin therapy is required while the blood sugar balance must be monitored around the clock, for the rest of the life. Most patients have no measurable insulin production left a few years after diagnosis, and in turn significantly increases the risk of serious diabetes-related complications.

The need for disease-modifying drugs that can preserve and increase their own insulin production in type 1 diabetes is thus very large. Diamyd Medical's investigational drugs, Diamyd® and Remygen®, are being developed to meet the need for new drugs that can prevent future diabetes-related complications.

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, three 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. An investigator-initiated trial with GABA and Diamyd[®] in patients recently diagnosed with type 1 diabetes is also ongoing at the University of Alabama at Birmingham, USA. 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 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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This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 14.45 CET on May 29, 2019.