



Press release, October 16, 2018

The Phase I/II trial with Remygen® for the regeneration of insulin-producing cells is recruiting patients

Recruitment of patients is ongoing to the first part of the clinical Phase I/II trial ReGenerate-1, with Diamyd Medical's orally administered GABA-based investigational drug Remygen®. The trial is conducted at Uppsala University Hospital and is directed at patients aged 18-50 years who have type 1 diabetes since more than five years and with low or non-existent insulin production.

"ReGenerate-1 is an exciting trial in type 1 diabetes," says Per-Ola Carlsson, Professor at Uppsala University and Uppsala University Hospital, Sponsor of the trial. "The trial gives us a unique opportunity to explore if and how the body can recreate its own insulin production using Remygen. It feels particularly special that we can offer patients who have type 1 diabetes since many years to be included in the trial, a group of patients who usually do not have the opportunity to participate in clinical trials due to their long-term illness."

ReGenerate-1 is an open label, investigator-initiated clinical trial encompassing a total of about 30 patients aged 18-50 years who have type 1 diabetes since more than five years with low to non-existing insulin production. The trial is conducted at Uppsala University Hospital with Professor Per-Ola Carlsson as the Principal Investigator. The trial consists of two parts; an initial safety and dose escalation part comprising six patients, and the main trial comprising 24 patients that will be followed for up to nine months depending on the dosage group they belong to. The primary aim is to evaluate the safety of Remygen®. The trial will also investigate whether Remygen® can regenerate insulin-producing cells, which ultimately would mean that patients can regain or increase their own insulin production. There are no trials so far that have evaluated the safety of GABA during pregnancy, and therefore women who can become pregnant will not be included in the trial.

"Through Remygen and the ReGenerate-1 trial, we take a further step forward towards a new type of diabetes treatment and towards achieving our vision that diabetes can be completely cured," says Ulf Hannelius, CEO of Diamyd Medical. "Diamyd to preserve insulin production, Remygen to build new insulin production."

About type 1 diabetes

Type 1 diabetes is an autoimmune disease where the beta cells, the cells in the pancreas that produce insulin, are broken down by the immune system. Type 1 diabetes has no cure and is associated with severe cardiovascular and long term complications such as acute low blood sugar (hypoglycaemia), cardiovascular problems, kidney damage and nerve damage that lead to major human suffering and high costs to society.

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

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

About Remygen®

Remygen® is a tablet based on the active substance GABA (gamma aminobutyric acid). The insulin producing cells in the pancreas also produce GABA and express GABA receptors. In type 1 and type 2 diabetes, researchers have found that levels of GABA may differ from those of healthy individuals and that the GABA receptor functionality in the pancreas has changed.

Preclinical data show that GABA stimulates growth and function of insulin-producing beta cells. Data also show that GABA's effect on beta cell growth and on the immune system can be further enhanced by adding other substances that affect the GABA receptors. In addition, research has also shown that GABA can increase insulin

sensitivity and control inflammation in metabolic syndrome and type 2 diabetes as well as mitigate disease progression in other inflammatory diseases such as rheumatoid arthritis.

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®, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in trials 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 investigational drug. An investigator-initiated trial in patients with type 1 diabetes since at least five years has started at Uppsala University Hospital. 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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