Press Release, 24 August 2020

Clinical trial with Remygen® is expanded to evaluate prevention of hypoglycaemia

The Swedish Medical Products Agency has approved an amendment to ReGenerate-1 to investigate Remygen®'s preventive effects on hypoglycaemia (severely reduced blood sugar level) in individuals with long-term type 1 diabetes.

”With this amendment to the study protocol, we can investigate in detail both Remygen's stimulating effects on the insulin-producing cells as well as its effect as a hypoglycemia-preventing drug, alone and together with Alprazolam”, says Per-Ola Carlsson, Professor at Uppsala University and Akademiska sjukhuset, Sponsor of the trial.

The results of the initial safety and dose escalation part of the Phase I/II trial ReGenerate-1 announced in May this year indicated a good safety profile and could also show that Remygen® improved the hormonal protection mechanisms that counteract hypoglycemia. The findings in the trial are patent pending. The main part of the trial is now underway, where treatment with Remygen® and Remygen® together with Alprazolam is tested for a period of six months.

“This development is exciting, says Ulf Hannelius, CEO of Diamyd Medical. “The surprising clinical findings from the first part of the trial with the respect to the prevention of hypoglycemia are valuable for Diamyd Medical and have given us reason to act quickly to evaluate additional product paths based on Remygen”.

About ReGenerate-1
ReGenerate-1 is an open-label, investigator initiated clinical trial involving a total of about 36 patients aged 18-50 who have had type 1 diabetes for longer than five years with low to non-existing residual insulin production. The trial is conducted at Uppsala University Hospital with Professor Per-Ola Carlsson as Principal Investigator. The trial consists of two parts; an initial safety and dose escalation part 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® and the combination of Remygen® and the GABA receptor-modulating substance Alprazolam. The trial will also examine whether Remygen® alone and in combination with Alprazolam can have a positive effect on the hormonal counter-regulatory response to low blood sugar and on the restoration of beta cell function, potentially allowing in the long run a patient to regain insulin producing capacity.

As previously announced, a positive safety review of Remygen® based on the initial safety and dose escalation part has allowed the initiation of the now ongoing main part of ReGenerate-1. The entire trial is expected to be completed in 2022 and interim analyses will be performed on a number of earlier occasions.

About Remygen®
Remygen® is Diamyd Medical’s proprietary formualtion of GABA, a key cell signalling molecule in the islets of Langerhans found in the pancreas. GABA has been shown to affect the secretion of insulin and glucagon both in healthy volunteers and in patients. Preclinical studies have shown strong indications that GABA stimulates the growth and function of the insulin and glucagon producing cells in the pancreas. Preclinical studies have also shown that GABA receptor modulating agents such as Alprazolam may increase the positive effect of GABA on the insulin producing cells.

About type 1 diabetes
Type 1 diabetes is an autoimmune disease whrere the beta cells, the cells of the pancreas that produces insulin, are broken down by the immune system. There is no cure for type 1 diabetes and the disease is associated with serious short and long term complications, such as acute low blood sugar (hypoglycaemia), cardiovascular problems, kidney damage and nerve damage, leading to great human suffering and high costs to society. When the disease is diagnosed, the patient has only about 20% left of the endogenous insulin production - an acute life-threatening condition. Life-sustaining insulin therapy is required while the blood sugar balance must be moniteored around

the clock, for the rest of life. Most patients have no measurable insulin production remaining a few years after diagnosis which increases the risk of serious diabetes-related complications.

About Diamyd Medical
Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is 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 significant effect in some pre-specified subgroups. Results from the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes, are expected to be presented at the end of September. A new facility for vaccine manufacturing is being set up in Umeå with the first priority to receive the process technology for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. 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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