Press Release, January 14, 2021

Positive safety evaluation of Remygen® in high dose and in combination with Alprazolam gives the go-ahead for the continuation of the trial

Following evaluation of safety data, an independent safety committee (DSMB) recommends the continuation of the investigator-initiated clinical trial ReGenerate-1, where Diamyd Medical's GABA-based study drug Remygen® is administered in combination with the GABA receptor modulator Alprazolam.

The evaluation was performed on safety data from four study participants in the group receiving a high dose of Remygen® and four in the group receiving a high dose of Remygen® in combination with Alprazolam, all of whom received treatment for one month. DSMB identified no safety issues and recommends that the trial continues according to plan.

”I am happy to see that we have also advanced this step in the development of Remygen and our GABA platform where the ReGenerate-1 trial is central to being able to prioritize the next step towards the market,” said Ulf Hannelius, CEO of Diamyd Medical.

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. Significant results have been shown in a genetically predefined patient group in a large-scale metaanalysis as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. A new facility for vaccine manufacturing is being set up in Umeå 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.

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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The information was submitted for publication, through the agency of the contact person set out above, at 12:30 CET on January 14, 2021.