Press release, November 11, 2019

Positive safety review of Remygen® gives clearance to start next part of Phase I/II trial in type 1 diabetes patients

The initial safety and dose escalation part of the Phase I/II trial with Remygen® in type 1 diabetes patients, ReGenerate-1, has been completed. The safety data from the six patients included in this first part of the trial has been evaluated by an independent Data Safety Monitoring Board (DSMB) who recommends that the main study can start. Metabolic results from the now completed safety and dose escalation part are being compiled and will be presented later this year.

"We already have the first participants ready to enter the next part of the trial," says Per-Ola Carlsson, Professor at Uppsala University and Uppsala University Hospital, Sponsor of the trial. ”We are now analyzing the results of the first part and intend to present them before year-end.”

The main part of ReGenerate-1 consists of three arms evaluating two different doses of Diamyd Medical's GABA-based study drug Remygen® and the ombination of Remygen® with the GABA receptor modulating substance Alprazolam. The safety of Remygen® and of the combination of Remygen® and Alprazolam will continue to be evaluated by the DSMB during the trial.

“This first positive safety review of Remygen® is important and lays a good foundation for the continuing efficacy trials,” says Ulf Hannelius, CEO of Diamyd Medical.

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 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®, 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 beta cell function, and in the long run allow a patient to regain insulin producing ability.

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 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, two 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. 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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The information was submitted for publication, through the agency of the contact person set out above, at 14.05 CET on November 11, 2019.