Press release, May 4, 2020

Promising findings from the first part of a clinical trial with Remygen®

The initial safety and dose escalation part of the Phase I/II trial ReGenerate-1 with Remygen® in individuals with long-term type 1 diabetes today presents preliminary results showing that the trial participants' blood sugar control improved over the nine-day treatment period. The results also support a surprising protective effect of Remygen® during hypoglycaemia, that is, during sharply lowered blood sugar levels. The findings in the trial are patent pending. The independent Data Safety Monitoring Board (DSMB) has previously approved the commencement of the main part of ReGenerate-1, which among other things evaluates Remygens® effect on restoring beta cell function.

"We are pleasantly surprised by these interesting findings with Remygen," says Per-Ola Carlsson, Professor at Uppsala University and Uppsala University Hospital, Sponsor of the trial. "We will now examine the results in detail and also look at the possibilities of verifying them in a larger patient material."

The six trial participants were treated with increasing doses of Remygen® for nine days to evaluate the safety of Remygen®, pharmacokinetic properties and metabolic responses. Before and during the treatment period, the trial participants' blood sugar values were monitored continuously with a so-called continuous blood glucose monitor. The patent-pending results show that the time that the participants spent in the target range for blood sugar increased during the treatment. The trial participants' responses to hypoglycemia were also evaluated before and during the treatment period with hyperinsulinemic hypoglycemic clamp, which means that the blood sugar is lowered under controlled forms and the body's hormonal response is measured. The results surprisingly show that the protective mechanisms that counteract hypoglycemia improved during the treatment period.

"Exciting and unexpected results," says Ulf Hannelius, CEO of Diamyd Medical. "Hypoglycemia is a significant problem in diabetes and the new findings provide preliminary support for the possibility of developing a preventive treatment with Remygen for hypoglycemia."

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 longer than five years with low to non-existing 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® and the combination of Remygen® and the receptor-modulating substance 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 capacity.

As previously announced, a positive safety review of Remygen® based on the initial safety and dose escalation part has given clearance to start the now ongoing main part of ReGenerate-1.

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 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 in the third quarter of 2020. 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® 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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