



Press Release, November 13, 2020

Previous findings from a clinical trial with Remygen[®] are discussed as part of a lecture on World Diabetes Day

Results from the initial dose escalation part of the phase I/II trial ReGenerate-1 with the study drug Remygen[®], which were announced in May this year, will be discussed by the trial's Sponsor and Principal Investigator Professor Per-Ola Carlsson during a web lecture to be held at Lund University in connection with World Diabetes Day on Saturday 14 November 2020.

The results that will be discussed show that Remygen[®] improved the hormonal protection mechanisms that counteract hypoglycaemia. More specifically, the results show that during hypoglycaemia, the secretion of the hormones glucagon, adrenaline, growth hormone and cortisol, increased after treatment with Remygen[®]. The effect of these hormones during hypoglycaemia is to counter the fall in blood sugar and the results provide support for a possible protective effect of Remygen[®] against hypoglycaemia.

Professor Carlsson's lecture, entitled "Stem cells, regenerative medicine and artificial intelligence in type 1 diabetes", can be followed via the link <https://www.youtube.com/watch?v=BN-v8KCvxqQ&feature=youtu.be> The lecture is part of the World Diabetes Day 2020 organized by the Diabetes Association in Skåne County, Lund University's Diabetes Center, Medeon and Diabetes Collaboration Sweden . Per-Ola Carlsson will give his presentation in Swedish at 11:10. See <https://vddskane.com/> for detailed program.

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 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 metastudy as well as in 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. 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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