Press Release, October 12, 2021

Clinical results with Diamyd Medical's study drug Remygen® published in scientific journal

The clinical results from the dose-escalation part of the investigator-initiated clinical Phase I/II trial ReGenerate-1 evaluting Remygen® (GABA) in individuals with long-standing type 1 diabetes, have been published in the scientific journal BMJ Open Diabetes & Care. The patent-pending findings showed, as previously announced, that Remygen® established a counter-regulatory response to severely reduced blood sugar levels (hypoglycemia), indicating its potential use as a hypoglycemia-preventing treatment.

Six trial participants in ReGenerate-1 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 (CGM).

The trial participants' responses to hypoglycemia were evaluated before and during the treatment period with hyperinsulinemic hypoglycemic clamp, which means that the blood sugar was lowered under controlled forms and the body's hormonal response was measured. As previously announced, the results showed that the protective mechanisms that counteract hypoglycemia, e.g. adrenaline, cortisol and glucagon responses, improved during the treatment period. The patent-pending results from the dose-escalation part also showed that the time that the participants spent in the target range for blood sugar tended to increase during the treatment.

The results are published in the article "GABA induces a hormonal counter-regulatory response in subjects with long-standing type 1 diabetes" that can be accessed at https://drc.bmj.com/content/9/1/e002442.

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.

About Diamyd Medical
Diamyd Medical develops precision medicine 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 large genetically predefined patient group in a large-scale meta-analysis 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. Preparations for a confirmatory Phase III trial in the US and Europe are on-going, to start recruting patients later in 2021. A vaccine manufacturing facility 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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