Press Release, May 10, 2023

Topline results from Remygen® trial in individuals with long-term Type 1 Diabetes

Uppsala University Hospital's ReGenerate-1 trial evaluating Diamyd Medical's Remygen® in individuals with long-term Type 1 Diabetes met the primary endpoint of safety. No clear support for a durable treatment effect on increasing endogenous insulin production measured as C-peptide or preventing hypoglycemia (sharply lowered blood glucose levels) by improving the protective counterregulatory hormonal response was observed. A potential trend for an immediate effect, e.g directly following ingestion of Remygen®, on improving counterregulatory hormonal responses was observed in the higher dose groups.

"These results did not provide clear evidence of a durable treatment effect with the evaluated doses in patients with long-term type 1 diabetes, says Per-Ola Carlsson, Professor at Uppsala University and Uppsala University Hospital and Principal Investigator of the trial. However, we continue to explore these and upcoming additional data to evaluate the potential trends seen for the immediate effects at the higher doses".

"As the Renerate-l trial includes only active control arms, no firm conclusions regarding potential efficacy signals can be drawn based on this initial set of topline results, says Ulf Hannelius, CEO of Diamyd Medical. This trial's primary endpoint was that of safety across a range of doses in individuals with very low or no endogenous insulin production. The data are important and we will continue to analyse the data. GABA, the active component in Remygen, has previously been evaluated in new-onset patients where the amount of endogenous insulin production is significantly higher. The amount of endogenous inslun production or the profile of the individual based on HLA genetics, may be important factors that remain to be explored regarding GABA:s mechanism of action. As communicated previously, Diamyd Medical's primary focus is the precision medicine antigen-specfic immunotherapy Diamyd and the international Phase 3 trial DIAGNODE-3".

The primary endpoint in ReGenerate-1 was safety and the main secondary endpoints evaluated the treatment effect on the hormonal counter-regulatory response to low blood sugar and on the restoration of beta cell function measured as stimulated C-peptide. The trial participants' responses to hypoglycemia were evaluated with a hyperinsulinemic hypoglycemic clamp, which means that the blood glucose is lowered under controlled forms and the body's hormonal response is measured. The topline results include full data from up to nine months of follow-up from 26 study participants assigned to one of three study arms: low-dose Remygen®, high-dose Remygen®, or high-dose Remygen® combined with low-dose Alprazolam.

No safety concerns where reported in the trial. No durable effect of Remygen® regarding increasing secretion of the hormones glucagon, adrenaline, growth hormone and cortisol during hypoglycemia was observed, indicating no apparent durable disease-modifying effect of the treatment. However, a potential trend for an immediate effect in the higher dose groups was observed on improving the counterregulatory hormonal response during hypoglycemia.

Treatment with Remygen® did not indicate a clear effect in terms of increasing endogenous insulin producing capacity measured as stimulated C-peptide. This said, individuals with some detectable insulin producing capacity at baseline retained their C-peptide for the duration of the trial. Individuals that had no detectable insulin producing capacity at baseline did not see a measurable increase in C-peptide during the trial.

Additional results pertaining to blood glucose control measured as HbA1c, Time in Range measured using continuous glucose monitoring and immunological markers, are expected in the coming weeks.

About Remygen®
Remygen® is Diamyd Medical's proprietary formulation 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 with recent onset type 1 diabetes. Preclinical studies have shown 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 ReGenerate-1
ReGenerate-1 was an open-label, investigator initiated clinical trial involving a total of 35 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 was conducted at Uppsala University Hospital with Professor Per-Ola Carlsson as Principal Investigator. The trial consisted of two parts; an initial safety and dose escalation part comprising six patients, and the main trial, which comprises 35 patients who will be followed up to nine months depending on the dose group to which they belonged. The main purpose was to evaluate the safety of Remygen® and the combination of Remygen® and the GABA receptor-modulating substance Alprazolam. The trial also examined whether Remygen® alone or in combination with Alprazolam had 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. Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruting patients with recent-onset Type 1 Diabetes in eight European countries and is being prepared to start recruiting patients in the US this summer. Significant results have previously 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 Diamyd® was administered directly into a lymph node in children and young adults with recently diagnosed Type 1 Diabetes. A biomanufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the antigen-specific immunotherapy 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. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB as well as in the artificial intelligence company MainlyAI 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.

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