



Press Release, April 20, 2023

## Minor timeline revision for Remygen® trial topline results

*The topline results from Uppsala University Hospital's ReGenerate-1 trial, which evaluates the safety and efficacy of Diamyd Medical's study drug Remygen® in individuals with Type 1 Diabetes, are expected in the first half of May 2023, reflecting a small revision to accommodate additional time required for completing statistical analyses by the contract research organization contracted by Uppsala University Hospital. The topline results will include data on endogenous insulin producing capacity measured as stimulated C-peptide and hormonal response to hypoglycemia. Additional results including blood sugar control measured as HbA1c and data from continuous glucose monitoring are expected during the second half of May.*

"The results will be announced in time for the IDS, BIO and ADA conferences taking place at the end of May and during June", says Ulf Hannelius, CEO of Diamyd Medical. "These conferences will provide excellent platforms to update both the scientific community as well as potential investors and partners on Remygen, our second clinical asset developed in parallel to our flagship candidate, the precision medicine antigen-specific immunotherapy Diamyd".

The topline results will include data from up to 9 months of follow-up from 35 study participants assigned to one of three study arms: low-dose Remygen®, high-dose Remygen®, or high-dose Remygen® combined with low-dose Alprazolam. The results of the initial dose escalation part of ReGenerate-1 in which six study participants were treated with increasing doses of Remygen® for nine days were presented in the publication *GABA induces a hormonal counterregulatory response in subjects with long-standing type 1 diabetes* which can be accessed at <https://drc.bmj.com/content/9/1/e002442>.

### 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. 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 ReGenerate-1

ReGenerate-1 is 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 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 35 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 or 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. Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruiting 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. An investigator-initiated Remygen® trial in individuals 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 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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