



Press release, December 17, 2019

## **Update from the Phase I/II trial ReGenerate-1 with Remygen®**

*The main part of the Phase I/II trial ReGenerate-1 with Remygen® in type 1 diabetes patients has started and four patients are already included in the trial. Additional patients are scheduled to be included in December and January. Compilation of metabolic results from the completed safety and dose escalation part of the trial awaits a final experimental analysis and is expected to be announced in early 2020.*

“The recruitment to the main trial is going well and in light of the interesting findings previously shown with GABA in both preclinical and clinical trials, we look forward to being able to submit the first results from ReGenerate-1 to a scientific conference shortly,” says Per-Ola Carlsson, Professor at Uppsala University and Uppsala University Hospital, Sponsor of the trial.

### **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 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 type 1 diabetes**

Type 1 diabetes is an autoimmune disease where the beta cells, the cells of the pancreas that produces insulin, are broken down by the immune system. There is no cure for type 1 diabetes and the disease is associated with serious short and long term complications, such as acute low blood sugar (hypoglycaemia), cardiovascular problems, kidney damage and nerve damage leading to great human suffering and high costs to society. When the disease is diagnosed, the patient has only about 20% left of the endogenous insulin production, an acute life-threatening condition. Life-sustaining insulin therapy is required while the blood sugar balance must be monitored around the clock, for the rest of life. Most patients have no measurable insulin production remaining a few years after diagnosis which increases the risk of serious diabetes-related complications.

### **About Diamyd Medical**

Diamyd Medical develops the diabetes vaccine Diamyd®, as 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 effect in some pre-specified subgroups. Besides the Company’s own European Phase IIb trial DIAGNODE-2 where the diabetes vaccine is administered directly into a lymph node, two investigator initiated clinical trials are ongoing with 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](mailto:info@fnca.se).

**For further information, please contact:**

Ulf Hannelius, President and CEO

Phone: +46 736 35 42 41

E-mail: [ulf.hannelius@diamyd.com](mailto:ulf.hannelius@diamyd.com)

**Diamyd Medical AB (publ)**

Kungsgatan 29, SE-111 56 Stockholm, Sweden. Phone: +46 8 661 00 26, Fax: +46 8 661 63 68

E-mail: [info@diamyd.com](mailto:info@diamyd.com) Reg. no.: 556242-3797 Website: <https://www.diamyd.com>

The information was submitted for publication, through the agency of the contact person set out above, at 15.55 CET on December 17, 2019.