



Press release, June 13, 2018

Diamyd Medical's Remygen™ for regeneration of insulin-producing cells approved for clinical trials

The Swedish Medical Products Agency has approved the initiation of the clinical Phase I/II trial ReGenerate-1, with Diamyd Medical's patent-pending study drug Remygen™. In addition to evaluating the safety of the study drug, the trial will investigate Remygen's ability to regenerate insulin-producing beta cells in patients with diabetes who have little or no endogenous insulin production.

"The positive decision by the MPA is very pleasing and a significant milestone for us as a company as we now have two study drugs, Diamyd® and Remygen™, in clinical phase," says Ulf Hannelius, CEO of Diamyd Medical. "Recovery of beta cell mass in patients with diabetes becomes so much more important now, especially as preliminary results with our patent-pending intralymphatic immunotherapy with the diabetes vaccine Diamyd® shows a downregulation of the autoimmune attack on insulin-producing cells. Remygen™ broadens our targeted patient group significantly as we can also address those who have had type 1 diabetes for many years, focusing on recovering lost insulin production."

"The concept to tackle type 1 diabetes with GABA-related drugs is very interesting," says Professor Per-Ola Carlsson, Department of Medical Cell Biology and Department of Medical Sciences, Uppsala University and Department of Endocrinology and Diabetology, Uppsala University Hospital. "If we are able to show increased beta cell mass with this treatment, entirely new opportunities will open up for patients with type 1 diabetes."

The investigator-initiated clinical trial ReGenerate-1 will be conducted at Uppsala University Hospital with Professor Per-Ola Carlsson as Principal Investigator. This is the first clinical trial where Diamyd Medical's own oral GABA-based study drug, Remygen™, is being tested. The aim of the trial is to evaluate the safety of Remygen™ as well as to investigate whether insulin-producing cells can be regenerated in patients who have had type 1 diabetes more than five years.

About ReGenerate-1

ReGenerate-1 is an open-label, investigator-initiated clinical trial encompassing a total of about 30 patients. The trial consists of two parts; an initial safety and dose escalation section comprising six patients, and the main trial, comprising 24 patients. The trial will include patients aged 18-50 who have had type 1 diabetes for more than five years with low to non-existing insulin production. There are so far no studies that have evaluated the safety of GABA in pregnancy, and therefore women who may become pregnant will not be included in the trial. In the main trial, patients will be randomized to two different doses of Remygen™ and monitored for up to nine months depending on which dose group they belong to. The primary aim of the trial is to evaluate the safety of Remygen™. The trial will also evaluate whether the insulin-producing cells can be regenerated using Remygen™, which in the long term would mean that patients can regain or increase their own insulin production.

About Diamyd Medical

Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, with its patent-pending technology for antigen-specific intralymphatic immunotherapy (AS-ILIT) based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in studies with more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company's own European Phase II trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymph node, there are four investigator initiated clinical trials ongoing with Diamyd®. Diamyd Medical also develops Remygen™, an oral GABA-based study drug. An investigator- initiated placebo-controlled trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is ongoing at the University of Alabama at Birmingham. Exclusive licenses for GABA and positive allosteric modulators of GABA receptors for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine Diamyd® and Remygen™ key assets. Diamyd Medical is also 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 and in the gene therapy company Periphagen, Inc., Pittsburgh, USA.

Diamyd Medical's B-share is traded on Nasdaq First North under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

For further information, please contact:

Ulf Hannelius, President and CEO

Phone: +46 736 35 42 41

E-mail: 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 Reg. no.: 556242-3797 Website: <https://www.diamyd.com>

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