



Press release, December 20, 2018

75 percent of patients now enrolled in Diamyd Medical's European Phase II trial

Three quarters, 80 out of 106 patients, are included in the European Phase II trial DIAGNODE-2, where the diabetes vaccine Diamyd® is administered directly into the lymph node. In January, a new clinic is expected to open for recruitment in Rotterdam, the Netherlands.

“The interest in DIAGNODE-2 continues to be high,” says Ulf Hannelius, CEO of Diamyd Medical. “The goal is a fully recruited trial in the first quarter of 2019. I would like to wish everyone Happy Holidays and best wishes for the New Year.”

About type 1 diabetes

Type 1 diabetes is an autoimmune disease where the beta cells, the cells in the pancreas that produce insulin, are broken down by the immune system. GAD65 (glutamic acid decarboxylase) is an endogenous protein that is expressed by the beta cells. In autoimmune diabetes, the immune system identifies the protein as dangerous and attacks and destroys the insulin-producing cells. GAD65 is the active ingredient in the diabetes vaccine Diamyd® being developed with the aim to reduce the immune system's sensitivity to GAD65 and thus preserving the remaining insulin production.

About DIAGNODE-2

The placebo-controlled trial DIAGNODE-2 encompasses approximately 106 patients from Spain, the Czech Republic, Sweden and the Netherlands, aged 12–24 years. The patients, recently diagnosed with type 1 diabetes are given the diabetes vaccine Diamyd® (or its placebo) directly into the lymph node on three occasions, one month apart, in combination with oral vitamin D (or its placebo) during four months, starting 30 days prior to the first injection. The patients are followed for 15 months with the aim to evaluate the remaining insulin producing capacity. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University. Sponsor for the trial is Diamyd Medical.

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®, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in trials 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 investigational drug. An investigator-initiated trial in patients with type 1 diabetes since at least five years has started at Uppsala University Hospital. 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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