



Press release, May 16, 2018

Swedish MPA approves an additional injection of Diamyd® in ongoing clinical pilot trial

The Swedish MPA has approved an extension of DIAGNODE-1, an open label clinical pilot trial where the diabetes vaccine Diamyd® is administered directly into the lymph node. The extension refers to three adult patients included in the trial who now will be offered a fourth injection of Diamyd®.

“The approval gives us the opportunity to evaluate the safety and immune response of a fourth so called booster injection, and whether we can further extend the effect of intralymphatic Diamyd® treatment on preserving the endogenous insulin production”, says Johnny Ludvigsson, Professor at Linköping University and Sponsor of DIAGNODE-1.

The patients will, starting this fall, be offered to participate in the extension, which means that they will receive a fourth injection of Diamyd® (4µg per dose) directly into the lymph node approximately 2.5 years after commencing their participation in the trial. The objective of the extension is to evaluate the safety of receiving a fourth injection and the effects on the immune system and the ability to produce insulin. After the fourth injection, patients will be followed for an additional 11 months.

Diamyd Medical has filed a patent application on the concept of treating patients with extra intralymphatic injections depending on their individual immunological and clinical response.

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 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: www.diamyd.com

This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 14:15 CET on May 16, 2018.