



Press release, April 11, 2019

Immunological findings supporting intralymphatic treatment with Diamyd® to be presented today at a diabetes meeting in Stockholm

A new analysis of results from the DIAGNODE-1 trial that supports the association between immunological and clinical response following intralymphatic administration of Diamyd® will be presented today at the Scandinavian Society for Study of Diabetes meeting in Stockholm.

The immunological findings are in alignment with previously announced results from DIAGNODE-1, showing that antigen-specific increase in the secretion of the cytokine IL-10, decreased cell proliferation and activation of GAD65-specific T-lymphocytes as well as an altered antibody response to GAD65, associate with clinical response at 15 months following intralymphatic treatment with Diamyd®. The results indicate that the immune response is characterized by tolerance to the antigen GAD65, the active component in Diamyd®, and support the positive clinical results that have previously been reported from the trial.

The results will be presented this Thursday afternoon in an oral presentation entitled “Immunological effects of GAD-alum injection into the lymph node in recent onset type 1 diabetes” during the annual scientific meeting organized by the Scandinavian Society for the Study of Diabetes.

<https://www.scandinaviandiabetes.org/meetings>

About DIAGNODE-1

DIAGNODE-1 is an open investigator initiated clinical pilot trial that comprises a total of twelve patients between 12 and 30 years with newly diagnosed type 1 diabetes, where the diabetes vaccine Diamyd® is injected on three occasions at a monthly interval with a low (4µg) dose directly into the lymph node (intralymphatically). The treatment is combined with oral vitamin D. The trial is designed to evaluate the safety, immunological response and clinical effect of the treatment, with readouts at 6, 15 and 30 month follow-up. The aim of intralymphatic treatment with Diamyd® is to preserve the endogenous insulin production by interrupting the autoimmune process in the body that destroys the insulin-producing cells. Johnny Ludvigsson, Professor at Linköping University is Sponsor of the trial.

DIAGNODE-1 has paved the way for the double-blind and placebo-controlled trial DIAGNODE-2 that started in November 2017 with the aim of verifying the results from DIAGNODE-1. The trial encompasses 106 patients and is conducted at clinics in Spain, the Czech Republic, the Netherlands and Sweden.

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, four 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. An investigator-initiated trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is also ongoing at the University of Alabama at Birmingham, USA. 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 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.

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