



Press release, October 23, 2018

## New immunological results that support intralymphatic treatment with Diamyd® to be presented at the Immunology of Diabetes Society Congress

*New results of intralymphatic treatment with the diabetes vaccine Diamyd® indicate the induction of a long-term immune response that supports the positive clinical results shown in the DIAGNODE-1 trial. The results are presented this week at the international conference Immunology of Diabetes Society Congress 2018 in London.*

"The results are encouraging and strengthen previously published immunological and clinical findings," says Rosaura Casas, Associate Professor of experimental pediatric immunology at Linköping University. "The most interesting finding is that intralymphatic treatment with GAD can create a specific and lasting shift in the body's immune response."

The new data is based on the immune response after 15 months follow-up of all twelve patients from the ongoing clinical trial DIAGNODE-1. The results show that three low doses of Diamyd® administered directly into the lymph node give rise to an increased and altered antibody response to the antigen GAD65, the active component of Diamyd®. The antibody increase is characterized by a relative decrease in the antibody subclass IgG1 while the subclasses IgG2, IgG3 and IgG4 increase. Increased antigen-specific secretion of the cytokine IL-10 in parallel with a decrease in antigen-induced cell proliferation and decreased activation of T cells indicates that the immune response after 15 months is characterized by tolerance to the antigen GAD65.

"Together with the clinical results previously reported and the ongoing phase IIb trial DIAGNODE-2, intralymphatic treatment with Diamyd® is at the forefront internationally and has great potential to be the first treatment approved to preserve the endogenous insulin production in type 1 diabetes," says Ulf Hannelius, CEO of Diamyd Medical.

The results will be presented during the Immunology of Diabetes Society Congress 2018 ([www.ids2018.org](http://www.ids2018.org)) in the form of a scientific poster: "Immunological effect of GAD-alum injection into the lymph node in recent onset Type 1 diabetes", authored by researchers at Linköping University and Munich University. The clinical results from DIAGNODE-1, press released by Diamyd Medical in September this year, are also presented at the conference in the poster: "Autoantigen (GAD-alum) given to lymph nodes together with oral Vitamin D to preserve beta cell function in type 1 diabetes - The DIAGNODE-1 pilot trial", authored by researchers at Linköping University.

### 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. Type 1 diabetes has no cure and is associated with severe cardiovascular and long term complications such as acute low blood sugar (hypoglycaemia), cardiovascular problems, kidney damage and nerve damage that lead to major human suffering and high costs to society.

When the disease is diagnosed, the patient only has about 20% of the endogenous insulin production left, an acute life threatening condition. Life-sustaining insulin therapy is required and the blood sugar balance must be monitored around the clock for the rest of one's life. Most patients have no measurable insulin production left a few years after diagnosis which in turn significantly increases the risk of serious diabetes-related complications.

The need for disease-modifying drugs that can preserve and increase insulin production in type 1 diabetes is therefore very high. Diamyd Medical's investigational drugs, Diamyd® and Remygen®, are being developed to meet the need for new drugs that are able to prevent future diabetes related complications.

### About DIAGNODE-1

DIAGNODE-1 is an open 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 (4 $\mu$ g) 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.

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 and Sweden.

### **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.

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