



Press Release, March 27, 2018

## **Diamyd<sup>®</sup> subcutaneously continues to show weaker results than when administered intralymphatically**

*A preliminary 15-month interim report from EDCR IIa, an investigator initiated pilot trial where the diabetes vaccine Diamyd<sup>®</sup> is administered subcutaneously in combination with etanercept and vitamin D shows, when all 20 patients have been followed for fifteen months, that the treatment is safe and tolerable. No serious side effects have been reported. Results pertaining to the patients' own insulin production, HbA1c and external insulin requirements are, however, weaker in EDCR IIa than from the ongoing DIAGNODE-1 trial where the diabetes vaccine is administered directly into the lymphnode.*

When all 20 patients had been followed for 15 months in the EDCR IIa trial, endogenous insulin production (measured as stimulated C-peptide) had decreased on average by 54% (compared to 10.4% in the DIAGNODE-1 trial when 9 patients have performed their 15 month visit), and fasting C-peptide had decreased by 45% (compared to an increase of 15% in DIAGNODE-1). Furthermore, HbA1c had on average increased by 7% (compared to a decrease of 24% in DIAGNODE-1) and external insulin requirement had increased by 72% (compared to a decrease of 19% in DIAGNODE-1). The treatment has been safe and tolerable and no serious side effects have been reported. Preliminary 15 month results from DIAGNODE-1 for 9 patients were press released on March 12, 2018.

"Even though some patients have had a positive clinical course with low blood sugar levels and limited need of externally administered insulin, the combination with etanercept has so far not shown any convincing effect on a group level," says Johnny Ludvigsson, Professor at Linköping University and Sponsor of EDCR IIa.

"The results from EDCR IIa up to 15 months further confirms our choice to focus on intralymphatic treatment, where both clinical and immunological results from DIAGNODE-1 look considerably stronger than the trials performed so far with subcutaneous administration," says Ulf Hannelius, CEO of Diamyd Medical.

### **About EDCT IIa**

The Phase II trial EDCR IIa (Etanercept-Diamyd<sup>®</sup>-Combination-Regimen) is being conducted at eight pediatric diabetes clinics in Sweden. The trial is an open label clinical pilot trial in children and adolescents between 8 and 18 years of age, newly diagnosed with type 1 diabetes, in which the diabetes vaccine Diamyd<sup>®</sup> is combined with two already approved substances, etanercept and vitamin D. The patients will be followed for a total of 30 months. The aim of the study is to evaluate the safety of the combination treatment as well as its impact on the immune system.

### **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<sup>®</sup>, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Diamyd<sup>®</sup> 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<sup>®</sup>. Diamyd Medical also develops Remygen<sup>™</sup>, an oral GABA-based study drug. An investigator initiated placebo controlled trial with GABA and Diamyd<sup>®</sup> 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<sup>®</sup> and Remygen<sup>™</sup> 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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