Press release, April 16, 2019

Results from the EDCR IIa trial where Diamyd® is given subcutaneously

30-month results from EDCR IIa, an investigator initiated pilot trial in which the diabetes vaccine Diamyd® is given subcutaneously combined with etanercept and vitamin D, show that the treatment is safe and tolerable. No serious side effects have been reported. As expected, based on previously reported 15-month results, the results at 30 months show no clear positive effect on the clinical course of the disease.

When all 20 patients had been followed for 30 months in the EDCR IIa trial, endogeonus insulin production (measured as stimulated C-peptide) had decreased on average by 70% and fasting C-peptide had decreased by 63%. Furthermore, the long-term blood glucose level HbA1c had on average increased by 17% and external insulin requirements increased by 111%. The treatment has been safe and tolerable and no serious side effects have been reported.

"The results from the trial further strenghten our view that the method of administration of Diamyd® is crucial for achieving a clinically relevant effect," says Ulf Hannelius, CEO of Diamyd Medical. "When Diamyd® is given under the skin, as in EDCR IIa, the same promising treatment effect is not achieved as when the diabetes vaccine is given intralymphatically as in the DIAGNODE-1 trial, where we have seen very promising clinical and immunological results."

"The combination with etanercept and Diamyd® subcutaneously did not show any convincing effect on a group level," says Johnny Ludvigsson, Professor at Linköping University and Sponsor for EDCR IIa. "Immunological analyzes from the trial will, however, be important in examining the treatment effect at the individual level."

About EDCR IIa

The Phase II trial EDCR IIa (Etanercept-Diamyd®-Combination-Regimen) has been conducted at eight pediatric diabetes clinics in Sweden. The trial was 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 subcutaneous administration (under the skin) of the diabetes vaccine Diamyd® was combined with two already approved substances, the immunosuppressive drug etanercept and vitamin D. The patients have now been followed for the whole study period, a total of 30 months. The aim of the study has been to to evaluate the safety of the combination treatment as well as its impact on the immune system and the patient's insulin producing capacity.

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, three 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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