Press Release, September 1, 2020

Analyses of prevention trials and intralymphatic pilot trial with the diabetes vaccine Diamyd® support a positive trend in genetically defined subgroups of type 1 diabetes

A combined analysis of two previous clinical prevention trials, DiAPREV-IT 1 and 2 in healthy children at high risk of type 1 diabetes, as well as additional insights from the open label pilot trial DIAGNODE-1 in children and young adults newly diagnosed with type 1 diabetes, while not reaching statistical significance, are consistent with the recently published large-scale responder analysis which showed a highly significant and clinically relevant effect of the diabetes vaccine Diamyd® in individuals positive for for genotypes that include HLA DR3-DQ2.

HLA analysis of DiAPREV-IT 1 and 2

Data from the investigator initiated clinical trials DiAPREV-IT 1 and DiAPREV-IT 2, together comprising 76 healthy children at high risk of type 1 diabetes, were analyzed to evaluate if the presence or absence of HLA-type DR3-DQ2 influence the effect of two subcutaneous injections of the diabetes vaccine Diamyd® compared to placebo on delaying the time to type 1 diabetes diagnosis. In total, 40 out of 76 individuals were positive for HLA-type DR3-DQ2, which is consistent with previous announced findings from a large-scale metastudy recently published in Diabetologia that showed an approximate occurance of 50% of that HLA-type in GAD autoantibody positive individuals with type 1 diabetes.

The effect estimate, while not reaching statistical significance, supports a positive effect of subcutaneous injections of Diamyd® on delaying the progression to type 1 diabetes in individuals positive for HLA-type DR3-DQ2 while no benefit compared to placebo is seen in individuals negative for HLA-type DR3-DQ2.

“The data from these trials in healthy individuals at risk for type 1 diabetes are limited but it is comforting that we still see consistent positive trends regarding Diamyd responder subgroups”, says Ulf Hannelius, CEO of Diamyd Medical.

HLA analysis of DIAGNODE-1

Data from the investigator initiated open label pilot trial DIAGNODE-1 comprising 12 individuals newly diagnosed with type 1 diabetes treated with intralympahtic injections of Diamyd®, were descriptively analyzed by grouping the individuals based on HLA genotype. In total, 6 out of 12 individuals were positive for HLA-type DR3-DQ2, which is consistent with previous announced findings from the metastudy published in Diabetologia that showed an approximate occurance of 50% of that HLA-type in GAD autoantibody positive individuals with type 1 diabetes.

The HLA groups were comparable at 15 and 30 months post baseline regarding preserved endogenous insulin production. The three patients who received an extra Diamyd® injection into the lymph node after their 30-month visit resulting in maintained endogenous insulin production between the 30- and 43-month visits, were all positive for HLA-type DR3-DQ2.

”These insights regarding HLA and the extra intralymphatic injection are of course intriguing, and we look forward to the DIAGNODE-2 results later in September to see if intralymphatic administration is superior to subcutaneous injections”, says Ulf Hannelius, CEO of Diamyd Medical.

About Diamyd Medical

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is 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 significant effect in some pre-specified subgroups. Results from the Company’s European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes, are expected to be presented at the end of September. A new facility for vaccine manufacturing is being set up in Umeå with the first priority to receive the process technology for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to

hypoglycaemia. An investigator-initiated Remygen® trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. 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 Growth Market 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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