Press Release, 27 August 2020

Diamyd Medical updates on DIAGNODE-2 and upcoming Phase III trial with the diabetes vaccine Diamyd®

The database for the European Phase IIb trial DIAGNODE-2 where the diabetes vaccine Diamyd® (rhGAD65 / alum) is given directly into the lymph node will be closed within the next few days. As previously announced, the top line results from the trial are expected to be presented at the end of September. The results from DIAGNODE-2 will affect the final design of the upcoming Phase III trial with Diamyd® regarding study population and route of administration.

When the database has been locked, the code will be broken and the data analyzed by an external statistician. The main results of DIAGNODE-2 will include both the primary clinical efficacy end-point; endogenous insulin production measured as stimulated C-peptide, and the most important secondary clinical end-points; long-term blood sugar measured as HbA1c, insulin dose and insulin-adjusted HbA1c. The results will be presented for the entire patient population as well as for the genetically defined subgroup HLA-type DR3-DQ2, which was identified in a previously reported meta-study based on three previous clinical trials, recently published in the scientific journal Diabetologia.

"We have the advantage of having access to large amounts of efficacy and safety data from all previous clinical trials that have evaluated the diabetes vaccine Diamyd", says Ulf Hannelius, CEO of Diamyd Medical. "The DIAGNODE-2 results will give us the opportunity to, together with these data and our insights on subgroups, route of administration and dosage, optimize the design of the upcoming phase III trial clinically and commercially".

Ongoing planning for the Phase III trial takes into account three possible main tracks: 1) intralymphatic administration of Diamyd® in individuals with newly diagnosed type 1 diabetes, 2) intralymphatic administration of Diamyd® in individuals with newly diagnosed type 1 diabetes and with HLA type DR3-DQ2, and 3) subcutaneous administration of Diamyd® in individuals with newly diagnosed type 1 diabetes and with HLA type DR3-DQ2. In light of the previously announced positive clinical results following an extra intralymphatic injection in the pilot trial DIAGNODE-1 as well as the dose-response relatonship identified in the recent Diabetologia publication, the possibility of giving an additional injection of Diamyd® is also being evaluated.

The patient population and route of administration in the Phase III trial will be decided after the results of DIAGNODE-2 have been analyzed. What will be evaluated is whether 1) data provide support for an effect in the entire patient population, 2) data show that an effect is driven by the genetically defined subgroup and whether 3) data provide support for intralymphatic administration leading to further improved effect in the genetically defined subgroup compared to subcutaneous administration. In addition to clinical data, regulatory, commercial and manufacturing-specific aspects will also be considered in the final design of the trial.

About DIAGNODE-2
The placebo-controlled trial DIAGNODE-2 encompasses 109 patients from Spain, the Czech Republic, Sweden and the Netherlands, aged 12−24 years. The patients, recently diagnosed with type 1 diabetes, have been given the diabetes vaccine Diamyd® (or its placebo) directly into the lymph node on three occasions, one month apart, in combination with oral vitamin D (or its placebo) during four months, starting 30 days prior to the first injection. The patients have been followed for 15 months with the aim to evaluate the remaining insulin producing capacity. As of the autumn of 2019, patients who had not yet completed their last visit at 15 months were offered to participate in an extension of the study for another 9 months. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University. Sponsor for the trial is Diamyd Medical. For more information about the trial, see www.diagnode-2.com.

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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