Press release, July 13, 2020

All patients have completed their 15-month visits in the European Phase IIb trial with the diabetes vaccine Diamyd®

Diamyd Medical's Phase IIb trial DIAGNODE-2 with the diabetes vaccine Diamyd® (GAD65-alum) is expected to present Topline results at the end of September. All patients in the trial where Diamyd® is given directly into the lymph node have completed their 15-month visits according to plan.

"We have seen a great deal of interest and commitment to the trial from our trial participants, clinics and collaboration partners", says Johnny Ludvigsson, Professor at Linköping University and Coordinating Investigator for the trial. "There is a great need for new treatments for type 1 diabetes. The fact that we are able to keep to the schedule in these COVID-19 times feels extra good and the pandemic makes it clear once again how important the safety profile of the Diamyd vaccine is, and that the treatment is simple for both patients and healthcare providers."

The collected data will now undergo extensive quality control at the clinics and in the electronic database. The database will then be locked whereafter the code will be broken and the data analysed. The Topline results from DIAGNODE-2 will include the primary clinical endpoints; endogenous insulin production measured as stimulated C-peptide, as well as the main secondary clinical endpoints; long-term blood sugar HbA1c, insulin dose and Partial remission measured as insulin-adjusted HbA1c.

The results will be presented for the entire patient population and for the genetically defined subgroups identified in a previously reported meta-study based on three previous clinical trials. The meta-study, reported in December 2019, included more than 500 patients and showed a statistically significant and dose-dependent effect of Diamyd® in maintaining endogenous insulin production in trial participants with a specific HLA genotype. The genetically defined subgroup of patients comprised approximately half of all patients included in the meta-study.

Topline results from DIAGNODE-2 are expected to be presented at the end of September. Additional results, including immunology, are expected to be reported a few months after the Topline results.

"We look forward to the results from DIAGNODE-2 which will support the final design of our upcoming Phase III trial with Diamyd®", says Ulf Hannelius, CEO of Diamyd Medical. "It will be especially important to evaluate if and to what extent the trial participants' HLA genotype influences the treatment effect of intralymphatic administration as we have previously seen with subcutaneous administration."

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® 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. 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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