



Press Release, April 15, 2021

## **Diamyd Medical contracts global CRO for Phase III trial with the diabetes vaccine Diamyd®**

*Diamyd Medical has contracted the global contract research organization (CRO) ICON plc for DIAGNODE-3, a placebo-controlled Phase III precision medicine trial with the diabetes vaccine Diamyd®. The trial is designed to confirm the efficacy and safety of Diamyd® in individuals recently diagnosed with type 1 diabetes who carry the genetically defined haplotype HLA DR3-DQ2. The trial is expected to begin recruiting patients later this year.*

“We have gotten to know ICON as a very skilled and committed collaboration partner during the preparation of our Phase III trial,” says Ulf Hannelius, CEO of Diamyd Medical. “Now we take the next critical step together with a focus on precision medicine for type 1 diabetes, and with over SEK 200 million in cash, we can move full speed ahead with getting the trial started in all countries and clinics.”

DIAGNODE-3 will include approximately 330 individuals aged 12 to 28 who have been recently diagnosed with type 1 diabetes and who carry the genetically defined haplotype HLA DR3-DQ2. The target population of the trial has been selected taking into account clinical efficacy and safety results from the Phase IIa and Phase IIb trials DIAGNODE-1 and DIAGNODE-2, as well as the large-scale meta-analysis that includes data from more than 600 individuals from previous Phase II and Phase III trials with Diamyd®.

The trial will be conducted at approximately 50 clinics in Europe and the United States, where almost half of all individuals with type 1 diabetes are estimated to carry the selected haplotype. After an initial month in which all trial participants receive vitamin D, the subjects will be randomized 2:1, ie two out of three trial participants will receive three intralymphatic injections of Diamyd® and one in three will receive the corresponding placebo at one month intervals, with one primary reading 24 months after study start. The design provides, based on efficacy data from previous trials in the HLA-restricted patient population, a high probability of reaching the primary efficacy endpoints; preservation of stimulated C-peptide and lower HbA1c. The Coordinating Investigator for the trial is Professor Johnny Ludvigsson at Linköping University.

The work with ICON is now focused on contracting the clinics, applying for approval to conduct the trial from the Competent Authorities and Ethics Committees in each country and other activities necessary to begin the recruitment of patients during the latter part of 2021.

### **About ICON**

ICON is a leading global provider of consulting, and outsourced development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisations. ICON has been recognised as one of the world’s leading Contract Research Organisations through a number of high-profile industry awards. Since ICON’s foundation in Dublin, Ireland in 1990, the company’s mission has been to help clients to accelerate the development of drugs and devices that save lives and improve quality of life.

### **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. Significant results have been shown in a genetically predefined patient group in a large-scale meta-analysis as well as in the Company’s European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. A new facility for vaccine manufacturing is being set up in Umeå 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.

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](mailto:info@fnca.se)

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The information was provided by the contact person above, for publication on April 15, 2021, 12.10 CET.