Press Release, June 16, 2021

24-month follow-up of Phase IIb Diamyd® clinical trial indicates continued similar progression after 15 months

50 out of the 109 individuals in DIAGNODE-2 who were included in an extension study have now been followed for a total of 24 months. The actively treated individuals carrying HLA DR3-DQ2, in total 15 individuals, followed their expected trajectory from 15 to 24 month, showing no indication of diminishing treatment effect compared to their progression up to to 15 months. As also expected, safety at 24 months looks good with no difference in adverse events between actively treated and placebo treated individuals.

As was disclosed in April 2021, no formal statistical analysis has been performed for the individuals included in the extension study, as the number of subjects is a small non-random sample and includes less than 50% of the original study population. The 15 actively treated individuals carrying the HLA DR3-DQ2 haplotype declined 22% in stimulated C-peptide between 15 and 24 months, and the 8 placebo treated individuals carrying the HLA DR3-DQ2 haplotype declined 38%.

"These data, while based on a small non-random sample of individuals indicate as expected that there are no drastic changes between 15 and 24 months in the actively treated DR3-DQ2 group, supporting the 24 month design in the upcoming precision phase 3 trial DIAGNODE-3," says Ulf Hannelius, CEO of Diamyd Medical. "We look forward to analyzing the immunological profile of the individuals followed for 24 months to see if we can detect profiles that associate with specific disease trajectories that could guide development of booster regimens."

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.

About DIAGNODE-3
The placebo-controlled Phase III trial 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 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 current haplotype. After an initial month in which all trial participants receive vitamin D, the individuals 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 trial start. The design provides, based on efficacy data from previous studies on the HLA-restricted patient population, a high probability of reaching the primary end-points; preservation of stimulated C-peptide and lower HbA1c. The Coordinating Investigator for the trial is Professor Johnny Ludvigsson at Linköping University. The Sponsor of the trial is Diamyd Medical.

About Diamyd Medical
Diamyd Medical develops precision medicine 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. Preparations for a confirmatory Phase III trial in the US and Europe are on-going, to start recruting patients later in 2021. 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.

For further information, please contact:
Ulf Hannelius, President and CEO
Phone: +46 736 35 42 41
E-mail: ulf.hannelius@diamyd.com

Diamyd Medical AB (publ)
Kungsgatan 29, SE-111 56 Stockholm, Sweden. Phone: +46 8 661 00 26, Fax: +46 8 661 63 68
E-mail: info@diamyd.com Reg. no.: 556242-3797 Website: https://www.diamyd.com

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