Press release, May 21, 2021

Diamyd® Phase IIb trial results published in Diabetes Care

Diabetes Care has published the results of DIAGNODE-2, a Phase IIb trial that evaluated intralymphatic administration of Diamyd Medical's lead drug candidate Diamyd® (GAD-alum) in individuals recently diagnosed with type 1 diabetes. Results showed, in line with a published large-scale metaanalysis of clinical data, that while no treatment benefit was seen in the full patient population, three intralymphatic injections of Diamyd® had a significant and positive effect on the preservation of insulin producing capacity in the predefined subgroup of individuals that carry the HLA DR3-DQ2 haplotype. In this subgroup of patients, more than 50% greater preservation of insulin producing capacity was observed at 15 months from baseline in those that received active treatment compared to placebo.

"We are proud to have the results from DIAGNODE-2 published in this leading diabetes journal", says Ulf Hannelius, CEO of Diamyd Medical. "The peer-reviewed publication provides important support for the notion that there is a well-defined group of individuals with type 1 diabetes that will benefit from precision treatment with the diabetes vaccine Diamyd®".

The article entitled "*Intralymphatic glutamic acid decarboxylase with Vitamin D supplementation in recent onset Type 1 diabetes: a double-blind randomized placebo-controlled Phase IIb trial*", showed that the primary endpoint of change in stimulated serum C-peptide was not met in the full analysis set of 109 individuals (treatment effect ratio 1.091, CI 0.845-1.408, p = 0.5009). However, in the predefined subgroup of individuals carrying HLA DR3-DQ2 (n=29), GAD-alum showed greater preservation of stimulated C-peptide (treatment effect ratio 1.557, CI 1.126-2.153, p = 0.0078) after 15 months compared to placebo treated individuals with the same genotype (n=17). Several secondary end points showed supporting trends and a positive effect was seen in terms of partial disease remission (IDAA1c≤9, p=0.0310). The results also show that HLA influences the immunological response to GAD-alum, the major consituant of Diamyd®. As expected with most vaccination efforts, minor transient injection site reactions were reported.

"DIAGNODE-2 has been integral to evaluate the safety and efficacy of intralymphatic injections of GAD-alum as well to prospectively evaluate the influence of HLA regarding the clinical and immunological effect of GAD-alum", says Johnny Ludvigsson, Professor at Linköping University. "There is a great unmet medical need in type 1 diabetes and with these data, superior safety profile and convenient treatment regimen, GAD-alum treatment shows strong promise in being able to change the treatment paradigm for this disease".

"This is an important milestone for the field of type 1 diabetes and a great example on the importance of merging scientific advances and insights with clinical development and data", says Mark Atkinson, Ph.D., Director of the Diabetes Research Institute at the University of Florida and Diamyd Medical Board Member. "Diligence and persistence with antigen specific therapies will bear fruit, and the notion that a precision vaccine approach, based on genetic markers, is the way forward to make a difference for type 1 diabetes".

The publication is available online at https://care.diabetesjournals.org/lookup/doi/10.2337/dc21-0318 and will later be published in an upcoming issue of the journal.

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. In addition to evaluating efficacy in the full patient population, individuals that carry the HLA DR3-DQ2 haplotype are predefined as a specific subgroup for safety and efficacy evaluation based on data from three previous placebo-controlled trials that indicate a significant influence of HLA on the efficacy of Diamyd®. 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 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