Press release, August 5, 2020

Diabetologia publishes results highlighting efficacy of the diabetes vaccine Diamyd® in genetically defined subgroups of type 1 diabetes

Diabetologia (the journal of the European Association for the Study of Diabetes [EASD]) has published results from a meta study that demonstrates a highly significant and clinically relevant effect of Diamyd Medical's lead drug candidate Diamyd® (GAD-alum) on preserving endogenous insulin production in genetically defined subgroups of type 1 diabetes. The meta study, first reported in December 2019, comprises more than 500 patients from three placebo controlled randomized clinical trials conducted in Europe and the USA assessing the therapeutic diabetes vaccine Diamyd® . The publication is co-authored by Dr. Ulf Hannelius, Diamyd Medical, Professor Craig Beam, Western Michigan University and Professor Johnny Ludvigsson, Linköping University.

"This peer-reviewed publication supports the findings that our immunomodulating, rather than immunosuppresive, antigen-specific therapy Diamyd® is effectively working in genetically defined subgroups", says Ulf Hannelius, CEO of Diamyd Medical. "These patent pending results on subgroups are very valuable for the company and will be analyzed as part of the topline results from the Phase IIb trial DIAGNODE-2 expected in September.

The Diabetologia article entitled "*Efficacy of GAD-alum immunotherapy associated with HLA DR3-DQ2 in recently diagnosed type 1 diabetes*", shows that the HLA genotype of individuals with type 1 diabetes influences the effect of GAD-alum. The published results demonstrate a significant and dose-dependent effect compared to placebo in individuals positive for all genotypes that include HLA DR3-DQ2 but not HLA-DR4-DQ8 and in a broader subgroup of individuals positive for genotypes that include HLA-DR3-DQ2,i.e. including those also positive for HLA DR4-DQ8. Higher doses,three or four subcutaneous injections, show a treatment effect ratio of 1.596 (95% CI 1.132, 2.249; adjusted p=0.0035) and 1.441 (95% CI 1.188, 1.749; adjusted p=0.0007) versus placebo for the two respective HLA subgroups.

"These results support decades of research on GAD-alum as a safe, specific and efficacious treatment for type 1 diabetes, says Johnny Ludvigsson, Professor at Linköping University. "A strong scientific and clinical rational makes me confident that we are now able to make a significant positive impact for individuals with type 1 diabetes".

Approximately 50% of all 521 individuals in the analysis were positive for genotypes that include HLA DR3-DQ2 and 25% of all individuals were positive for genotypes that include HLA DR3-DQ2 but not HLA-DR4-DQ8. Human Leukocyte Antigen (HLA) molecules are critical in mediating host defense responses through antigen presentation and immune tolerance. DR3-DQ2 and DR4-DQ8 are genetic variants that code for parts of HLA molecules that are present on professional antigen-presenting cells where they display short sequences of proteins, so called peptides, to other immune cells, most prominently T lymphocytes. DR3-DQ2 and DR4-DQ8 are both known to confer high risk of developing type 1 diabetes and DR3-DQ2 has previously been associated with autoimmunity to GAD while DR4-DQ8 has been associated with autoimmunity to insulin.

The now published results suggest that the best efficacy of antigen-specific immunotherapy may be achieved when targeting individuals that show a specific HLA type that is linked to the tolerizing antigen.

"For many years, there has been talk of so called 'personalized medicine', meaning giving the right drug to the appropriate person", says Mark Atkinson, Ph.D., Director of the Diabetes Research Institute at the University of Florida and Diamyd Medical Board Member. "The findings of this study are consistent with that notion and may serve as an example for attempts to prevent or cure type 1 diabetes as well as for other autoimmune disorders".

The publication is avalable at https://doi.org/10.1007/s00125-020-05227-z.

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 in the third quarter of 2020. 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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