



Press Release, April 20, 2022

New meta-analysis with Diamyd® published in scientific journal

An update of a large-scale meta-analysis supporting the efficacy of the therapeutic diabetes vaccine Diamyd® in individuals recently diagnosed with Type 1 Diabetes carrying the genetic HLA DR3-DQ2 haplotype has been published in the peer-reviewed scientific journal Diabetes, Obesity and Metabolism. The analysis shows that treatment effect with Diamyd® on the preservation of endogenous insulin production measured as C-peptide is associated with a beneficial treatment effect on blood glucose measured as HbA1c.

“To our knowledge, this is the first analysis that shows a clear association between positive treatment effects on C-peptide and blood glucose control in this patient population, providing further support for the clinical efficacy of the diabetes vaccine Diamyd in the genetic target population of Type 1 Diabetes patients with HLA DR3-DQ2, says Christoph Nowak, MD PhD, Medical & Data Officer at Diamyd Medical and first author of the recently published article. “The association also lends further support to the importance of C-peptide as a clinically meaningful surrogate endpoint in clinical trials, and strengthens our confidence in the primary endpoints of C-peptide and HbA1c in the confirmatory phase 3 trial DIAGNODE-3.

“These data are very important for the field of Type 1 Diabetes, supporting the clinical rationale of disease-modifying treatments that focus on preserving the individual’s own insulin production”, says Johnny Ludvigsson, Professor at Linköping University and senior author of the article.

The analysis is based on data from more than 600 individuals who participated in four placebo-controlled randomized clinical trials evaluating the effect of the therapeutic diabetes vaccine Diamyd® on preserving endogenous insulin production. The results support the notion that preservation of C-peptide using Diamyd® vaccine correlates with beneficial effects on HbA1c in individuals with recent-onset Type 1 Diabetes carrying the genetic haplotype HLA DR3-DQ2 and receiving standard of care diabetes treatment.

The article is published online in Diabetes, Obesity and Metabolism, a journal currently ranked 21st out of 145 in the Endocrine category, and can be accessed at <https://doi.org/10.1111/dom.14720>

The article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between the version available as of April 20, 2022, and the final version. A freely accessible Open Access version of the final article is expected to become available shortly.

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 large 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. DIAGNODE-3, a confirmatory Phase III trial is on-going. A vaccine manufacturing facility 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 individuals 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 as well as in the artificial intelligence company MainlyAI 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

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