



Press release, December 12, 2019

Significant effect of Diamyd® in Type 1 diabetes shown in a new comprehensive analysis of previous Phase III and Phase II trials

Diamyd Medical announces that a new analysis based on data from more than 530 individual patients from previous phase III and II trials in Europe and US with the diabetes vaccine Diamyd® has identified genetically defined subgroups of type 1 diabetes patients that show a positive and statistically significant dose-dependent treatment response.

In the analysis, patients who were positive for certain HLA genotypes and treated with the highest number of doses of Diamyd® (three and four subcutaneous injections) experienced a statistically significant treatment effect of approximately 60% compared to placebo at 15 months from baseline. Also, when treatments with low number and high number dose regimens (two, three and four subcutaneous doses) were combined, a statistically significant treatment effect of approximately 40% was seen.

“This has great significance for Diamyd Medical, type 1 diabetes research and the antigen-specific immunotherapy field in general”, says Mark Atkinson, Professor and Board member of Diamyd Medical. “These results support the notion that you can identify patients that will have a much higher likelihood to respond to a GAD-based therapy based on a well-known and scientifically plausible genetic profile. This finding has implications for both disease prevention as well as intervention trials in type 1 diabetes. I am encouraged that we are poised to advance a safe, specific and efficacious treatment that has the potential to significantly change the course of this disease.”

"The importance of today's announcement cannot be understated," says Ulf Hannelius, CEO of Diamyd Medical. "This finding strengthens the likelihood of success for the diabetes vaccine Diamyd® and will be taken into account in the analysis of the ongoing DIAGNODE-2 trial. Notably, in the phase IIb trial DIAGNODE-2 we are advancing intralymphatic administration of Diamyd® which we foresee to be even more efficacious than the subcutaneous route used in previous trials."

Professor Johnny Ludvigsson, Principal Investigator for the analysed Swedish Phase II and European Phase III trials and for the ongoing Phase IIb trial DIAGNODE-2 trial underlines the importance of these findings: “This may be a breakthrough step towards understanding how personalized medicine for autoimmune diseases will evolve. It is a great achievement to for the first time be able to identify a large cohort of patients that experience a significant effect of autoantigen-specific treatment.”

The analysis is based on data from more than 530 patients from three previously published trials: a European phase III trial, a Swedish phase II trial and a US phase II trial. The group showing the strongest response to the GAD-specific immunotherapy Diamyd® represented approximately 25% of the total number of patients involved in the analysis. Also, a more broadly defined responder subgroup, representing approximately 50% of the total number of patients, showed a statistically significant treatment response. The results will be submitted as an abstract to a scientific conference and are based on a collaborative effort between Diamyd Medical, academic researchers and clinicians.

About Diamyd Medical

Diamyd Medical develops the diabetes vaccine Diamyd®, as 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 effect in some pre-specified subgroups. Besides the Company's own European Phase IIb trial DIAGNODE-2 where the diabetes vaccine is administered directly into a lymph node, two investigator initiated clinical trials are ongoing with 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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