Press Release, October 26, 2023

Follow-up study suggests Diamyd® may offer advantages in delaying type 1 diabetes onset

A retrospective follow-up study of two prior randomized placebo-controlled trials (DiAPREV-IT and DiAPREV-IT2) indicates numerical benefits, although not statistically significant, favoring treatment with only two subcutaneous injections of Diamyd® on reducing the incidence of type 1 diabetes diagnosis (Stage 3) in healthy children at risk of type 1 diabetes (Stage 1 or Stage 2) carrying the HLA DR3-DQ2 haplotype. The study, encompassing a total of 76 children, out of which 40 carried the HLA DR3-DQ2 haplotype, had a maximum follow-up time of 13 years and was performed by Professor Helena Elding Larsson (Lund University and Skåne University Hospital).

"These results based on real world data are encouraging and provide additional support for Diamyd and our precision medicine approach in potentially delaying the onset of clinical type 1 diabetes in healthy children who are at high risk", says Ulf Hannelius, CEO of Diamyd Medical. "Today we know that there is a clear dose-response relation for Diamyd treatment, and the fact that we after only two subcutanous injections still see positive trends of benefits on the hard clinical outcome of time-to-diagnosis is very reassuring."

"In this small study, the trends are interesting and reassuring for further research studies evaluating a more optimized dose regimen", says Helena Elding-Larsson, Principal Investigator, Lund University and Skåne University Hospital.

Results
Out of a total of 76 individuals, the primary analysis was performed based on the 40 individuals carrying the HLA DR3-DQ2 haplotype. 18 individuals received two subcutaenous injections of Diamyd® and 22 received placebo. The average follow-up time was 7 years with some subjects followed up to 13 years. The preliminary results show that the estimated incidence rate of type 1 diabetes diagnosis, while not reaching statistical significance, was lower in Diamyd® treated individuals carrying the HLA DR3-DQ2 gene compared to placebo treated individuals. Also, in line with previously reported results, no benefit compared to placebo was seen in individuals negative for HLA DR3-DQ2, further highlighting the precision medicine approach employed with Diamyd®. Further analyses in the DR3-DQ2 group and full population are being conducted.

Diamyd Medical is currently initiating a Phase II clinical trial at the Clinical Research Centre at Lund University evaluating intralymphatic administration of Diamyd® in healthy children at risk for type 1 diabetes carrying HLA DR3-DQ2.

Previous information on Diamyd® in Stage 1 and Stage 2 type 1 diabetes
DiAPREV-IT (EudraCT 2008-007484-16) evaluated the effect of two subcutaneous injections of Diamyd® on preventing the progression to Stage 3 type 1 diabetes diagnosis in 50 children aged 4-<18 years positive for GADA and classified as Stage 1 or Stage 2 type 1 diabetes over a 5 year trial period compared to placebo. Results were presented in 2017 in Pediatric Diabetes (https://onlinelibrary.wiley.com/doi/10.1111/pedi.12611) . The results showed that GAD-Alum as a subcutaneous prime and boost injection was safe in prediabetic young children. but did not affect progression to type 1 diabetes.

DiAPREV-IT2 (EudraCT 2014-003755-64), was designed to enroll 80 children aged 4-<18 years positive for GADA and classified as Stage 1 or Stage 2 type 1 diabetes to be randomized to receive two subcutaneous injections of Diamyd or placebo and be followed over the course of five years. The trial was later shortened to follow 26 children for two years.

In September 2020 the meta-analysis of the combined data from DiAPREV-IT and DiAPREV-IT2 (https://www.diamyd.com/docs/pressClips.aspx?ClipID=3758915) showed that treatment with two subcutaneous injections of Diamyd®, while not reaching statistical significance, might have a positive effect on the progression

to type 1 diabetes in individuals positive for HLA DR3-DQ2 while no benefit compared to placebo was seen in individuals negative for HLA DR3-DQ2 in line with results from Diamyd® trials in recent onset type 1 diabetes.

About Diamyd Medical
Diamyd Medical develops precision medicine therapies for Type 1 Diabetes. Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruting patients with recent-onset Type 1 Diabetes in eight European countries and the US. Significant results have previously 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 Diamyd® was administered directly into a lymph node in children and young adults with recently diagnosed Type 1 Diabetes. A biomanufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the antigen-specific immunotherapy 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. 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.

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