Press Release, October 20, 2023

Preliminary results from Booster trial with Diamyd® provide additional support for intralymphatic injections

Preliminary results from the open-label clinical trial DIAGNODE-B provide additional support for the safety and feasibility of intralymphatic booster injections of Diamyd®, showing only a small decline in stimulated endogeous insulin production one year following the additional injection and up to 8 years from type 1 diabetes diagnosis.

"These results are valuable as they continue to support the feasibility of additional intralympahtic injections of Diamyd and a mild disease progression", says Johnny Ludvigsson, Professor at Linköping University and Sponsor's representative of the trial.

On average, the six individuals that received a booster injection had stable and well-controlled blood glucose levels measured as HbA1c. Average stimulated C-peptide, a measure of endogenous insulin secretion, was 0.66nmol/L before the first Diamyd® injection years ago, and now, one year following the booster injection, the decline was on average 0.03nmol/L. No serious adverse events were reported. The two individuals that received a fifth injection had a slow and stable progression over the almost 8 year follow-up with one individual retaining almost 50% of the endogenous insulin production during the total follow-up time.

"These and previous booster data are important in the plan for how Diamyd treatment could be used in long-term clinical practice, whether on an individual basis or as part of a more general booster regimen", says Ulf Hannelius, CEO of Diamyd Medical.

DIAGNODE-B is based on an earlier analysis of the DIAGNODE-1 trial, communicated on December 20, 2019, in which three patients received an additional intralymphatic Diamyd® injection after the 30-month visit. That analysis showed preservation of own insulin production between the 30-month and 43-month visits. A follow-up analysis, communicated on August 26, 2021, showed that all three individuals who received an additional injection in DIAGNODE-1 carried the genetic HLA DR3-DQ2 haplotype, a haplotype that has been associated with positive clinical response to Diamyd® treatment and is carried by up to 40% of individuals diagnosed with type 1 diabetes. The results were published in the peer-reviewed scientific journal Acta Diabetologica in January 2022 (https://doi.org/10.1007/s00592-022-01852-9).

DIAGNODE-B is an open-label investigator-initiated clinical trial in Type 1 diabetes patients who carry the genetically defined haplotype HLA DR3-DQ2 and have previously been treated with intralymphatic injections of Diamyd®. The trial includes six patiens who have either been treated with four injections in DIAGNODE-1, who have received a 5th intralymphatic injection of Diamyd®, or patients who participated in DIAGNODE-2, who have received a 4th intralymphatic injection of Diamyd®, approximately 4 years after the last injection. The aim of the trial is to evaluate the safety of a booster (fourth/fifth) injection of Diamyd® and the effect on the immune system and endogenous insulin production. The patients have been followed for 12 months after the additional injection. The trial is conducted at the Clincal Resarch Unit at the University Hospital in Linköping. Sponsor of the trial is Linköping University with Professor Johnny Ludvigsson as the Sponsor's representative. Diamyd Medical contributes with study drug, expertise and some financial support.

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 has started in 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.

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)
Box 7349, SE-103 90 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

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