Press Release, January 4, 2024

Diamyd® precision medicine Phase 3 trial key interim analysis in July

The upcoming interim analysis of the transformational gene-based precision medicine Phase 3 trial, DIAGNODE-3, for type 1 diabetes is planned for July 2024. This precision medicine trial employs the antigen-specific immunotherapy Diamyd® and the interim assessment, focusing on the preservation of endogenous insulin production as measured by C-peptide levels at 6 months follow-up, will include data from 70-80 patients presently enrolled in DIAGNODE-3. This analysis is an important milestone, providing insights into the trial's progress towards achieving its primary goals.

DIAGNODE-3, the first-ever precision medicine Phase 3 trial in this field, aims to confirm the efficacy and safety of Diamyd®. The treatment is designed to therapeutically preserve the function of the insulin producing pancreatic beta cells measured as C-peptide and maintain glycemic control in newly diagnosed patients with type 1 diabetes. Diamyd® has been granted Orphan Drug Designation by the FDA to treat type 1 diabetes in individuals with residual beta cell function. The current trial targets individuals who carry the HLA DR3-DQ2 haplotype - a genetic subgroup of this orphan indication with proven clinical response to Diamyd® in both retrospective and prospective studies (Hannelius et al 2020, Ludvigsson et al 2021, Nowak et al 2022, Nowak et al 2022). Importantly, the genetic subgroup aligns with the concept of endotypes in type 1 diabetes introduced in 2020 (Battaglia et al 2020).

The interim analysis will include 70-80 patients enrolled in DIAGNODE-3 who have completed their 6-month assessment and is planned to be reported at the latest in July 2024. The analysis will evaluate the probability of the trial meeting its primary objective regarding C-peptide preservation.

DIAGNODE-3 (Ludvigsson et al 2022) is designed to meet its co-primary endpoints of C-peptide and HbA1c with around 280 patients who completed the study over a 24-month period. For C-peptide as a standalone endpoint, about 150 patients are needed to achieve at least 90% statistical power. Ongoing assessments are being made to determine if an earlier unblinded readout in DIAGNODE-3 could support a request for accelerated approval based solely on C-peptide results. The trial is active in eight European countries and the United States, spanning 60 clinical sites, with additional sites in the US being initiated to expand the trial's reach and enhance recruitment, aiming for full enrollment by the end of 2024.

The body’s own insulin production capacity measured as C-peptide plays a critical role in managing glycemic control and reducing long-term complications associated with type 1 diabetes. A comprehensive meta-analysis recently published in The Lancet Diabetes & Endocrinology (Taylor et al 2023), encompassing data from approximately 2,700 newly diagnosed type 1 diabetes patients who participated in 21 trials evaluating disease-modifying therapies, underscores the significance of preserved C-peptide. This analysis, similar to a previous meta-analysis of clinical trial data with Diamyd® (Nowak et al 2022), showed a correlation between preserved C-peptide and improved blood glucose levels measured as HbA1c. Notably, these effects were observed as early as 6 months after baseline, aligning with DIAGNODE-3’s interim analysis timeline.

About Diamyd Medical
Diamyd Medical develops precision medicine therapies for the prevention and treatment of Type 1 Diabetes and LADA. 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 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, 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 protein, the active ingredient in the antigen-specific immunotherapy Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a component in treatments of metabolic diseases. Diamyd

Medical is a major shareholder 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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