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Diamyd Medical announces finalization of database for interim analysis in Phase 3 DIAGNODE-3 trial

The clinical database has been finalized for the pre-specified interim efficacy analysis in Diamyd Medical's ongoing pivotal Phase 3 trial (DIAGNODE-3) evaluating retogatein (rhGAD65) in individuals with Stage 3 type 1 diabetes. The outcome of interim analysis readout is expected by the end of March 2026.

“This is a key milestone in DIAGNODE-3 and for our precision medicine strategy in type 1 diabetes,” says Ulf Hannelius, President and CEO of Diamyd Medical. “The interim analysis will provide the first Phase 3 assessment of retogatein’s potential to preserve insulin production in a genetically defined patient population.”

The interim analysis is based on data from 174 evaluable participants. The primary endpoint of the interim analysis is change from baseline to Month 15 in stimulated C-peptide area under the curve (AUC), reflecting preservation of endogenous insulin production, and is intended to provide an assessment of treatment effect in the study population. In line with the company’s regulatory strategy, positive interim result would support engagement with regulatory authorities to discuss possible approval pathways for retogatein.

The interim analysis will assess the efficacy of retogatein compared to placebo and test whether predefined criteria for statistical significance are met. An independent Data Safety Monitoring Board (DSMB) will review the interim result and accumulated safety data. The company intends to communicate the outcome of the DSMB meeting, including whether statistical significance was met for the primary endpoint, as well as an update on the DSMB’s safety assessment of the ongoing trial.

DIAGNODE-3 is a randomized, double-blind, placebo-controlled confirmatory Phase 3 trial evaluating intralymphatic administration of retogatein formulated with alum in children, adolescents, and young adults newly diagnosed with Stage 3 type 1 diabetes who carry the HLA DR3-DQ2 haplotype. This genetic profile is present in approximately 40% of individuals with type 1 diabetes in Europe and the United States. The primary readout will be based on baseline to 15-month data for all randomized participants after which participants will continue to be followed for a total of 24 months. DIAGNODE-3 is expected to be fully randomized in mid-March 2026.

DIAGNODE-3 is supported, in part, by funding from Breakthrough T1D (formerly JDRF), the leading global type 1 diabetes research and advocacy organization.

Retogatein has received Fast Track Designation from the FDA for the treatment of type 1 diabetes across Stages 1–3, as well as Orphan Drug Designation for Stage 3 type 1 diabetes.

About Diamyd Medical

Diamyd Medical develops precision medicine therapies to prevent and treat type 1 diabetes. Retogatein (rhGAD65) formulated with alum is an investigational antigen-specific immunotherapy, designed to induce antigen-specific immune tolerance to GAD65 and preserve endogenous insulin production in individuals with type 1 diabetes who carry the HLA DR3-DQ2 gene. Retogatein has been granted Orphan Drug Designation in the U.S. as well as Fast Track Designation by the U.S. FDA for the treatment of Stage 3 (clinically diagnosed symptomatic) type 1 diabetes. Fast Track Designation has also been granted for the treatment of Stage 1 and 2 (pre-symptomatic) type 1 diabetes. DIAGNODE-3, a confirmatory Phase 3 trial with potential for an accelerated approval pathway in the US, is being conducted at 57 clinics in eight European countries and in the US in patients with recent-onset (Stage 3) type 1 diabetes. Significant results in preserving endogenous insulin production have previously been shown in a large genetically predefined patient group – both in a large-scale meta-analysis as well as in the Company’s prospective European Phase 2b trial. The DIAGNODE-3 trial has only included patients from this specific patient group that carries the common genotype known as HLA DR3-DQ2, which constitutes approximately 40 % of patients with type 1 diabetes in Europe and the US. A biomanufacturing facility is under development in Umeå, Sweden, for the manufacture of retogatein (recombinant GAD65 protein), the active ingredient in the antigen-specific immunotherapy. Diamyd Medical is a major shareholder in the stem cell company NextCell Pharma AB and 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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