Press release January 12, 2026

Diamyd Medical announces completion of screening in pivotal Phase 3 DIAGNODE-3 trial

Diamyd Medical today announced that the screening period in its pivotal Phase 3 DIAGNODE-3 trial evaluating retogatein (rhGAD65) in individuals with type 1 diabetes has been completed. Based on the number of patients screened, the Company expects approximately 310–320 participants to be randomized into the trial once enrollment is completed, which is expected by early March.

"The completion of screening is a key milestone for DIAGNODE-3 and confirms strong operational momentum in our pivotal genetically defined Phase 3 program," says Ulf Hannelius, CEO of Diamyd Medical. "With enrollment approaching completion and the primary efficacy readout accelerated following FDA alignment, we are entering a highly catalyst-rich period for the company."

DIAGNODE-3 is a randomized, double-blind, placebo-controlled Phase 3 trial evaluating retogatein (rhGAD65) in genetically defined individuals with Stage 3 type 1 diabetes. Retogatein is an investigational antigen-specific immunotherapy designed to preserve endogenous insulin production. By inducing antigen-specific immune tolerance to GAD65, retogatein aims to modulate the autoimmune response responsible for beta-cell destruction, potentially slowing or halting disease progression.

"DIAGNODE-3 represents the first precision-medicine Phase 3 study in type 1 diabetes to prospectively enroll patients based on a specific genetic profile," says Professor Johnny Ludvigsson, Coordinating Investigator of the DIAGNODE-3 trial. "The completion of screening reflects a strong commitment and consistent implementation at participating sites across Europe and the United States, and I would like to thank patients and their families, investigators and the study teams for their engagement in conducting this complex study."

As previously communicated, following a Type C meeting with the U.S. Food and Drug Administration (FDA), Diamyd Medical has aligned with the FDA to accelerate the primary efficacy readout in DIAGNODE-3 from 24 to 15 months, while maintaining a robust assessment of treatment efficacy. This adjustment enables the full primary efficacy data to be available approximately nine months earlier than originally planned.

The previously announced interim efficacy analysis, based on approximately 170 participants with 15-month follow-up, remains on track for the end of March 2026.

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 recombinant GAD65 protein, the active ingredient retogatein 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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