



Press release March 27, 2026

Diamyd Medical reports negative interim results of Phase 3 DIAGNODE-3 trial

Diamyd Medical today announced the completion of a pre-specified interim efficacy analysis on C-peptide in the ongoing pivotal Phase 3 DIAGNODE-3 trial evaluating retogatein (rhGAD65) in individuals with recent-onset Stage 3 type 1 diabetes carrying the HLA DR3-DQ2 haplotype. The interim analysis that included 174 out of 321 study participants did not demonstrate statistical significance on the primary endpoint at this timepoint. In addition to this, the pre-specified criteria required to support continuation of the trial were not met. No safety concerns were identified during the interim review. Diamyd Medical will provide an update with more information no later than Sunday the 29th of March 2026.

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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