Press release April 10, 2026

Diamyd Medical discontinues DIAGNODE-3 following evaluation confirming futility; initiates strategic review

Diamyd Medical today announced that it will discontinue the Phase 3 DIAGNODE-3 trial evaluating retogatein (rhGAD65) in Stage 3 type 1 diabetes. Following the previously reported interim analysis and subsequent evaluation of the interim results, including independent external statistical validation, the Company has concluded that the interim results meet the pre-specified futility criteria and do not support continuation.

The interim analysis results, first announced on Friday March 27, were based on 174 evaluable participants followed from baseline to month 15. The results showed no clinically meaningful effect on C-peptide, a marker for endogenous insulin secretion, in the overall population or in pre-specified subgroups. In addition to this, the pre-specified criteria required to support continuation of the trial were not met.

In an evaluation that included review of the data derivation, patient randomization, and statistical assumptions used for the interim analysis, no factors were identified that meaningfully affected the interpretation of the results. No new safety concerns have been identified. Available glycemic data, specifically HbA1c and Time in Range, are consistent with the C-peptide results and indicate a well-controlled patient population with no observable differences between the active and placebo arm at month 15.

Diamyd Medical will initiate an orderly wind-down of the trial that prioritizes patient safety and meets all ethical and regulatory requirements. The Company will proceed with unblinding of the dataset and conduct a comprehensive analysis to better understand the outcome.

The Company will assess the future potential and direction of its GAD-based immunotherapy program based on insights from this analysis.

Strategic review and operational focus
In parallel, the Board of Directors has initiated a formal review of the organization and strategic alternatives aimed at maximizing shareholder value. This includes evaluation of external assets, partnerships, and potential corporate transactions. The Company will also adjust its staffing and other costs to address the situation that has arisen.

As part of this review, Diamyd Medical will continue to maintain and evaluate its manufacturing capabilities at its fully owned biomanufacturing facility in Umeå, Sweden, including the ongoing GMP certification process. The Company will explore opportunities for the facility as a stand-alone biomanufacturing company.

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 in patients with recent-onset (Stage 3) type 1 diabetes was discontinued following a pre-planned interim futility analysis which indicated that the study was unlikely to meet its primary endpoint. 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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This information is information that Diamyd Medical is obliged to make public pursuant to the EU Market Abuse Regulation. The information was provided by the contact person above, for publication on 19.10 CET, April 10, 2026.