



Press release March 29, 2026

Diamyd Medical updates on the interim efficacy analysis of Phase 3 DIAGNODE-3 trial

Diamyd Medical on Friday March 27th announced that the pre-specified interim efficacy analysis on 174 out of 321 participants of the ongoing Phase 3 DIAGNODE-3 trial yielded results that were unexpected and not aligned with prior retrospective or prospective data. This lack of alignment underscores the need for thorough evaluation of the interim analysis results. Based on the interim dataset, no treatment effect on C-peptide was observed, neither in the overall population nor in pre-specified subgroups, including the previously identified potential super responder group.

“This outcome is highly unexpected and not consistent with the totality of prior data,” said Ulf Hannelius, CEO of Diamyd Medical. “The absence of any observable effect on C-peptide, including in pre-specified subgroups, makes it critical to conduct a thorough evaluation. Our priority is to understand these surprising findings that we received late on Friday and determine the most appropriate path forward.”

The Company will conduct a comprehensive assessment of the analysis results that were received late on Friday March 27. The Company’s core operations, including manufacturing activities, will continue as planned during this period.

To ensure patient safety and full compliance with ethical and regulatory standards Diamyd Medical will engage with regulatory authorities to determine appropriate next steps.

“The interim outcome is disappointing and not aligned with earlier results,” said Dr. Joshua Vieth, Senior Director of Research at Breakthrough T1D. “A thorough evaluation of the interim results will be essential to understand these findings. We support Diamyd Medical in this work that will inform next steps in the development of retogatein.”

Diamyd Medical will report further findings as analyses progress and will continue to communicate transparently on conclusions and next steps.

The Company will hold live conference calls tomorrow, Monday, March 30, 2026 at 8:30 am CET (Direkt Studios, link to access call at: <https://www.youtube.com/live/XPY2VdMUArI>) and 3:00 pm CET (DNB Carnegie, link to access call at: https://qcnl.tv/p/r0_qafjpYZQbdjGvj3SSYbg).

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.

For further information, please contact:

Ulf Hannelius, President and CEO

Phone: +46 736 35 42 41

E-mail: ulf.hannelius@diamyd.com

Diamyd Medical AB (publ)

Box 7349, SE-103 90 Stockholm, Sweden. Phone: +46 8 661 00 26, Fax: +46 8 661 63 68

E-mail: info@diamyd.com Reg. no.: 556242-3797 Website: <https://www.diamyd.com>

The information was provided by the contact person above, for publication on 22.45 CET, March 29, 2026.