Press release 27 July 2026

Diamyd Medical Provides Update on Learnings from DIAGNODE-3 Interim Analysis

Review identifies potential contributing factors and informs future development considerations; no new safety concerns identified.

- The pre-specified interim analysis included 174 of 321 enrolled participants at 15 months after the first study injection.
- The primary efficacy analysis did not achieve statistical significance, and the pre-specified continuation criteria were not met.
- The Company is closing DIAGNODE-3 for futility in accordance with the trial's pre-specified decision framework.
- No new safety concerns were identified in connection with the interim analysis or subsequent review.

Diamyd Medical AB (publ) today provided an update on learnings from its internal and external review of the pre-specified interim efficacy analysis from the pivotal Phase 3 DIAGNODE-3 trial. The trial evaluated the investigational antigen-specific immunotherapy retogatein (rhGAD65) in individuals with recent-onset Stage 3 type 1 diabetes carrying the HLA DR3-DQ2 haplotype.

As previously announced, the interim analysis included 174 of the 321 enrolled participants and assessed C-peptide at 15 months after the first study injection. The analysis did not demonstrate statistical significance on the primary efficacy endpoint. In addition, the pre-specified criteria for continuation of the trial were not met. Based on these results, the Company decided to close DIAGNODE-3 for futility. No safety concerns were identified.

Since receiving the interim results, Diamyd Medical has conducted a structured review of trial conduct, drug product characteristics, administration procedures, and available clinical data. The review did not identify any single reason, cause or design flaw that explains the outcome. No material protocol violations were identified. Instead, the review identified several factors that may warrant consideration in the design of any future preventive or therapeutic clinical study. These observations are hypothesis-generating and should not be interpreted as established explanations for the outcome of DIAGNODE-3.

- **Treatment administration:** Intralymphatic administration may be operationally demanding in a large, multicenter trial in which individual sites treat relatively few participants. Compiled evidence from clinical trials to date potentially favors the more robust subcutaneous administration method. Future protocols could consider enhanced training, documentation, and quality-control measures in case of intralymphatic administration of study drug.
- **Timing of treatment:** Exploratory analyses, and experience from other studies for the treatment of recent onset Stage-3 Type-1 Diabetes, suggest that a shorter interval between diagnosis and first treatment may be of merit. The available subgroups in DIAGNODE-3 were small and did not support definitive conclusions.

- **Drug product potency:** "The measured potency of the drug product used in DIAGNODE-3 appears to have been lower than that used in the preceding DIAGNODE-2 study. There was a clear immunological response resulting from exposure in DIAGNODE-3, and the clinical relevance of the difference in potency has not been established, but is a factor that should be considered in future trials."

- **Exploratory subgroup findings:** Numerical trends were observed in certain subgroups; however, these analyses were not powered for confirmatory inference and involved limited participant numbers. They should therefore be viewed as exploratory only.

Taken together, the review supports several potential lessons for future study design of antigen-specific tolerization studies with GAD65 as the active product ingredient in individuals with recent onset Stage-3 Type-1 Diabetes, including strengthened controls around intralymphatic administration, evaluation of earlier treatment after diagnosis, and further refinement of drug-product potency assessment. Any future clinical development would require an appropriately designed prospective study and engagement with relevant regulatory authorities.

> *"DIAGNODE-3 did not meet the pre-specified criteria required to continue, and we are acting on that result with scientific discipline and financial responsibility. Our review has not identified a single cause for the outcome, but it has generated important learnings regarding trial execution, treatment timing, and product characterization. These observations are exploratory and will require prospective validation. Retogatein has been administered to more than 1,000 participants across clinical studies, and no new safety concerns were identified in DIAGNODE-3. We will apply the lessons from this program as we evaluate strategic options for retogatein, our GAD65 manufacturing capabilities and the Company's broader assets."*
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> **— Anders Essen-Möller, Interim CEO, Diamyd Medical**

Diamyd Medical's GMP-certified biologics facility in Umeå continues its program and capabilities for the manufacture of recombinant GAD65 for investigational use. The Company is in parallel evaluating strategic opportunities related to its development assets, manufacturing platform, and potential partnerships. A decision to initiate a new clinical efficacy trial with retogatein for the prevention or treatment of AutoImmune Diabetes would be subject to scientific, regulatory, strategic, and financial assessment.

Forward-looking statements

This press release contains forward-looking statements, including statements regarding potential contributing factors to the DIAGNODE-3 outcome, possible future development activities, manufacturing opportunities, partnerships, and strategic options. Forward-looking statements are based on current expectations and assumptions and are subject to risks and uncertainties that may cause actual results to differ materially. Exploratory, post hoc and subgroup observations described in this release are hypothesis-generating and do not establish clinical efficacy or a causal explanation for the trial outcome. Readers should not place undue reliance on these statements. Diamyd Medical undertakes no obligation to update forward-looking statements except as required by applicable law or market rules.

About Diamyd Medical

Diamyd Medical is a Swedish biotechnology company focused on precision medicine approaches for type 1 diabetes and biological manufacturing. The company's investigational drug candidate retogatein, based on recombinant GAD65, was evaluated in the Phase 3 DIAGNODE-3 trial in recent-onset type 1 diabetes. The Company has established a facility for manufacturing of biological products in Umeå, Sweden.

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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