



Press release May 5, 2026

Diamyd Medical strengthens its position in the manufacturing of biological medicines – positive feedback from the Swedish Medical Products Agency

Diamyd Medical today announces a significant advancement in the company's operations related to the manufacturing of biological medicines (biologics). The company has successfully established manufacturing capacity in accordance with current quality requirements and regulatory guidelines, representing an important step in its continued development.

The company has also received positive feedback from the Swedish Medical Products Agency regarding a previously conducted inspection.

As a result, Diamyd Medical expects to obtain manufacturing authorization and a GMP (Good Manufacturing Practice) certificate in the near future, further verifying that production is carried out according to the highest international quality standards.

"This is a very important milestone for our production facility in Umeå," says Sofia Mayans, Head of Manufacturing Site. "The progress we are now making in manufacturing, regulatory processes, and quality assurance lays a strong foundation for our continued development. I am extremely proud of the dedication and work that the team at the facility has put in to make this possible."

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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