Press release December 12, 2025

Diamyd Medical finalizing Phase 3 screening as GMP review progresses

The number of randomized participants in DIAGNODE-3, Diamyd Medical's registrational Phase 3 trial in type 1 diabetes, has now exceeded 290, and the screening will conclude in the coming weeks. The interim efficacy analysis of approximately 170 participants with 15-month data is scheduled for end of March 2026. The Company also confirms that its Umeå manufacturing facility is currently under review by the Swedish Medical Products Agency as part of the GMP-certification process.

"Finalizing the screening phase is a major milestone and a significant achievement by all participating clinics in this first-of-its-kind precision-medicine Phase 3 trial in type 1 diabetes," says Ulf Hannelius, CEO of Diamyd Medical. "We are in good shape for the March 2026 interim efficacy readout, with DIAGNODE-3 having already passed multiple pre-scheduled safety reviews as well as a futility analysis. Moreover, the ongoing GMP review of our Umeå facility is a decisive step forward that strengthens the manufacturing foundation for the program and the company."

Enrollment continues to progress according to plan in DIAGNODE-3, the Company's registrational Phase 3 trial evaluating Diamyd® in individuals aged 12 to 28 with recently diagnosed Stage 3 type 1 diabetes carrying the HLA DR3-DQ2 genotype. With more than 290 participants enrolled and screening to conclude shortly, the study is approaching the planned interim efficacy readout. The interim efficacy analysis will include approximately 170 evaluable participants assessed after 15 months follow-up in the trial and focuses on stimulated C-peptide as an endpoint. The analysis was designed in alignment with FDA feedback to maintain the registrational integrity of the trial while enabling the potential for an accelerated Biologics Licensing Application.

The trial has previously passed several independent safety reviews and a futility analysis, each recommending continuation without modification.

Diamyd® is being developed as a precision-medicine, antigen-specific immunotherapy aimed at preserving endogenous insulin production in genetically defined individuals. The FDA has granted Fast Track Designation for Diamyd® across Stages 1–3 of type 1 diabetes, Orphan Drug Designation for Stage 3 type 1 diabetes, and has confirmed C-peptide as an acceptable surrogate endpoint that can support an accelerated approval pathway in the US.

The Company's 2,200 m² manufacturing facility—for the manufacture of recombinant GAD65, the active ingredient in Diamyd®—is currently under formal review for GMP certification from the Swedish Medical Products Agency. GMP certification will enable manufacture of clinical-grade material and represents an important step toward approval for commercial manufacturing as part of a Biologics Licensing Application.

About Diamyd Medical
Diamyd Medical develops precision medicine therapies to prevent and treat type 1 diabetes. Diamyd® is an investigational antigen-specific immunomodulatory therapeutic for the preservation of endogenous insulin production specifically for individuals carrying a HLA DR3-DQ2 gene. Diamyd® 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. Diamyd® has also been granted Fast Track Designation 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 actively recruiting patients with recent-onset (Stage 3) type 1 diabetes at 57 clinics in eight European countries and in the US. Significant results in preserving endogenous insulin production have previously been shown in a large genetically predefined patient group – both in a largescale meta-analysis as well as in the Company's prospective European Phase 2b trial. The DIAGNODE-3 trial is recruiting only this 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 recombinant GAD65 protein, the active ingredient in the antigen-specific immunotherapy Diamyd®. 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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