Press release November 14, 2025

Diamyd Medical's pivotal Phase 3 Type 1 Diabetes trial clears last safety review ahead of early readout in March 2026

The independent Data Safety Monitoring Board (DSMB) has completed its sixth scheduled safety review of Diamyd Medical's registrational Phase 3 trial, DIAGNODE-3, evaluating the precision medicine immunotherapy Diamyd®. The review identified no safety concerns and resulted in a recommendation to continue the trial as planned.

DIAGNODE-3 is conducted under Fast Track and Orphan Drug Designations granted by the U.S. Food and Drug Administration (FDA), with an agreement in place that an early efficacy readout planned for March 2026 may serve as the basis for a Biologics License Application (BLA) under the FDA's accelerated approval pathway.

"The continued favorable safety profile demonstrated in DIAGNODE-3 and earlier studies reinforces Diamyd's position as a leading precision medicine candidate in Type 1 Diabetes," says Professor Johnny Ludvigsson, Coordinating Investigator of DIAGNODE-3.

"Diamyd is uniquely positioned among late-stage disease-modifying therapies with the potential to change how Type 1 Diabetes is treated," says Ulf Hannelius, CEO of Diamyd Medical. "We look forward to the Phase 3 interim efficacy readout in March 2026."

The DSMB is an independent committee of clinical experts that monitors safety and efficacy in ongoing studies. This positive review further strengthens the favorable safety profile of Diamyd®. To date, 285 patients have been enrolled in DIAGNODE-3. Of these, more than 70 patients have completed the full 24-month follow-up, and more than 135 have completed their 15-month visit.

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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