Press release December 28, 2025

Diamyd Medical accelerates primary efficacy readout by 9 months in type 1 diabetes Phase 3 trial following FDA alignment and guidance

Diamyd Medical has reached alignment with the U.S. Food and Drug Administration (FDA) to accelerate the primary efficacy readout in its ongoing pivotal, registrational Phase 3 DIAGNODE-3 trial in type 1 diabetes from 24 to 15 months, per FDA guidance, enabling the full primary efficacy readout of the trial to occur nine months earlier than previously planned and communicated. The previously announced interim efficacy readout, involving approximately 170 participants with 15-month data, remains on track for the end of March 2026 and may support an accelerated BLA pathway, consistent with FDA guidance.

"We are very pleased with the FDA's feedback as it provides a clear way forward," says Ulf Hannelius, CEO of Diamyd Medical. "The proposed change meaningfully shortens the timeline to the full primary efficacy readout in our registrational Phase 3 trial, while maintaining a robust assessment of long-term efficacy. We remain focused on the upcoming interim efficacy readout in March 2026, which is on track as the next key catalyst in our efforts to bring this therapy to patients with type 1 diabetes."

The trial's co-primary efficacy endpoints, C-peptide area under the curve (AUC), a marker of endogenous insulin production, and HbA1c, a measure of blood sugar control, were originally defined at 24 months. Following a recent Type C meeting, and consistent with FDA guidance, the FDA agreed with the Company's proposal to change the timepoint for the primary efficacy readout to 15 months, with a formal protocol amendment to be submitted for FDA review. The originally planned 24-month assessment will be retained as a secondary endpoint to assess durability of the treatment effect of Diamyd®.

DIAGNODE-3 is a randomized, double-blind, placebo-controlled Phase 3 trial evaluating Diamyd® in approximately 300 genetically defined individuals with Stage 3 type 1 diabetes. Diamyd® is a precision-medicine, antigen-specific immunotherapy designed to preserve endogenous insulin production.

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 may support an accelerated approval pathway in the United States.

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 an 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 large-scale 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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