Press release January 9, 2026

# Diamyd Medical's lead immunotherapy for type 1 diabetes receives global non-proprietary name retogatein

*Diamyd Medical today announced that its investigational antigen-specific immunotherapy for type 1 diabetes, commonly referred to as Diamyd, has been assigned the global non-proprietary name "retogatein" by the World Health Organization's International Nonproprietary Names (INN) Programme and the United States Adopted Names Council (USAN).*

"The assignment of the non-proprietary name retogatein represents an important milestone in the development of our precision immunotherapy for type 1 diabetes," says Ulf Hannelius, CEO of Diamyd Medical. "The INN and USAN provide a standardized global identifier for the active substance, recombinant human GAD65, which is a cornerstone of our efforts to address the unmet needs of individuals living with type 1 diabetes. With the assignment of the INN/USAN name retogatein, we will use this non-proprietary name in our scientific, clinical, and corporate communications, while in parallel advancing the process toward a future trade name as we move closer to commercialization."

Retogatein (recombinant human GAD65; rhGAD65) formulated with alum is an antigen-specific immunotherapy developed as a precision-medicine for type 1 diabetes. Retogatein is designed to preserve endogenous insulin production in individuals with type 1 diabetes who carry a defined HLA genotype. By inducing antigen-specific immune tolerance to GAD65, retogatein aims to modulate the autoimmune response responsible for beta-cell destruction, potentially slowing or halting disease progression.

The therapy is currently being evaluated in the pivotal Phase 3 trial, DIAGNODE-3, in individuals with newly diagnosed Stage 3 type 1 diabetes, and has been granted Orphan Drug and Fast Track designations by the FDA.

The INN/USAN designation ensures a globally recognized non-proprietary name, ensuring consistent identification and communication in scientific, clinical, and regulatory settings worldwide

**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 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 retogatein 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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