Press release February 9, 2026

Diamyd Medical receives Notice of Allowance for key retogatein US patent

Diamyd Medical today announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for a patent covering the intralymphatic administration of retogatein (rhGAD65) with alum for the prevention and treatment of type 1 diabetes.

The now allowed U.S. application is part of a patent family with corresponding rights already granted in Europe, Australia, Hong Kong, China, Canada, South Africa, Japan, Russia, and Israel. Upon grant, the U.S. patent will further strengthen Diamyd Medical's international patent protection for a key component of its antigen-specific immunotherapy platform. The patent, when issued, will have an anticipated expiration date in 2035.

"This Notice of Allowance further strengthens our global intellectual property for our precision medicine and antigen-specific immunotherapy in type 1 diabetes," says Ulf Hannelius, President and CEO of Diamyd Medical. "Securing patent protection in the U.S. is a key milestone as retogatein advances toward potential commercialization."

The intralymphatic administration method protected by the patent is being used in the ongoing confirmatory Phase 3 DIAGNODE-3 trial in children, adolescents, and adults with newly diagnosed Stage 3 type 1 diabetes. An FDA-aligned interim efficacy readout from the trial is expected end of March 2026.

As a biological product, retogatein is eligible for regulatory market exclusivity in the United States and Europe, independent of patent protection, subject to regulatory approval.

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 being conducted at 57 clinics in eight European countries and in the US in patients with recent-onset (Stage 3) type 1 diabetes. 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.

For further information, please contact:
Ulf Hannelius, President and CEO
Phone: +46 736 35 42 41
E-mail: ulf.hannelus@diamyd.com

Diamyd Medical AB (publ)
Box 7349, SE-103 90 Stockholm, Sweden. Phone: +46 8 661 00 26, Fax: +46 8 661 63 68
E-mail: info@diamyd.com Reg. no.: 556242-3797 Website: https://www.diamyd.com

The information was provided by the contact person above, for publication on 08.45 CET, February 9, 2026.