



Press release March 2, 2026

American Diabetes Association 86th Scientific Sessions to feature retogatein Phase 3 trial in dedicated symposium

Diamyd Medical today announced that its pivotal Phase 3 DIAGNODE-3 trial evaluating retogatein (rhGAD65) in Stage 3 type 1 diabetes has been selected for a dedicated scientific symposium at the American Diabetes Association (ADA) 86th Scientific Sessions in New Orleans, June 5–8, 2026.

“Selection of DIAGNODE-3 for a dedicated symposium by the ADA 2026 Scientific Sessions planning committee is an honor and underscores the scientific importance of this Phase 3 program and the increasing recognition of precision medicine approaches in type 1 diabetes”, said Ulf Hannelius, President and CEO of Diamyd Medical.

Results from a pre-specified 15-month interim efficacy analysis in DIAGNODE-3 based on data from 174 evaluable participants are expected to be announced by the Company at the end of March 2026. The ADA symposium will present the study design, the scientific rationale for the precision medicine approach, and a discussion of these interim results.

The symposium, titled “Precision Medicine for New-Onset Type 1 Diabetes: Interim Phase 3 Outcomes of Retogatein (rhGAD65) Antigen Immunotherapy in DIAGNODE-3,” will be chaired by Dr. Emily Sims (Indiana University School of Medicine) and feature presentations from:

- Dr. Jason Gaglia (Harvard Medical School)
- Prof. Johnny Ludvigsson (Linköping University), and
- Dr. Thomas W. Donner (Johns Hopkins University School of Medicine)

Symposium Details

Title: Precision Medicine for New-Onset Type 1 Diabetes: Interim Phase 3 Outcomes of Retogatein (rhGAD65) Antigen Immunotherapy in DIAGNODE-3

Topic: Clinical Therapeutics

Date: June 8, 2026

Time: 3:15 PM – 4:15 PM (Central Time)

Program

3:15 PM – 3:30 PM

Clinical Benefits of Endogenous Insulin Preservation in Type 1 Diabetes

Speaker: Jason Gaglia, MD, MMSc; Harvard Medical School

3:30 PM – 3:45 PM

Clinical Development of a GAD65 Antigen-Specific Immunotherapy: Design of a Precision Medicine Phase 3 Trial Based on HLA Genetics

Speaker: Johnny Ludvigsson, MD, PhD; Linköping University

3:45 PM – 4:00 PM

15-Month Interim Safety and Efficacy Outcomes from the Phase 3 DIAGNODE-3 Trial

Speaker: Thomas W. Donner, MD; Johns Hopkins University School of Medicine

Further information is available in the ADA Scientific Sessions program: <https://epro02.ativ.me/appinfo.php?page=Session&project=ADA26&id=S175&server=epro02.ativ.me>

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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