



Press release, September 11, 2025

New analysis to be presented at EASD supports potential of Diamyd® to delay the progression of Stage 3 Type 1 Diabetes

A new retrospective analysis of clinical data from 241 individuals with Stage 3 Type 1 Diabetes carrying the HLA DR3-DQ2 genetic marker has been accepted for oral presentation at the European Association for the Study of Diabetes (EASD) Annual Meeting in Vienna, Austria, 15-19 September. The analysis reinforces previous findings, demonstrating that treatment with Diamyd® (rhGAD65/alum), a precision medicine immunotherapy currently being evaluated in the pivotal Phase 3 trial DIAGNODE-3, leads to longer preservation of insulin production compared to placebo.

The analysis combined data from three clinical trials involving 241 individuals (median age 13) diagnosed with stage 3 (clinically diagnosed symptomatic) type 1 diabetes within the last six months. All individuals carried the HLA DR3-DQ2 genetic marker and received either at least 3 injections of Diamyd® (as in the ongoing DIAGNODE-3 trial), 2 injections, or a placebo, on top of standard of care insulin treatment.

Key Findings

Treatment with at least 3 injections of Diamyd® significantly delayed the disease progression to an insulin response below 0.2 nmol/L ($p = 0.001$) – a level important for reducing future diabetes complications.

- In the placebo group, half of the participants dropped below 0.2 nmol/L after 14.6 months.
- For those receiving Diamyd®, fewer than half reached this level during the study, indicating that their insulin production was preserved for significantly longer.

Treatment with at least 3 injections of Diamyd® significantly delayed the disease progression to an insulin response below 0.5 nmol/L ($p = 0.015$) – a level linked to better blood sugar control.

- In the placebo group, half of the participants dropped below 0.5 nmol/L after 8.8 months.
- For those receiving at least 3 doses of Diamyd®, this decline took 14.5 months, showing that their insulin production was preserved for significantly longer.

These results support previously published retrospective and prospective results, and more clearly indicate that Diamyd® helps preserve the body's own ability to produce insulin above clinically defined levels in individuals carrying the genetic HLA DR3-DQ2 marker. Importantly, research shows that maintaining one's own insulin production, even below these thresholds, is important to reduce the risk of long-term diabetes complications.

"This analysis strengthens the case that Diamyd® can delay the progression of Type 1 Diabetes in individuals with type 1 diabetes with the HLA DR3-DQ2 genetic marker. We are eager to validate these findings in our ongoing registrational Phase 3 trial, DIAGNODE-3," said Ulf Hannelius, President and CEO of Diamyd Medical.

The findings will be presented on Thursday September 18 by Anton Lindqvist, CSO of Diamyd Medical, in the oral session "Next-generation therapeutics: novel approaches to diabetes and obesity" at the EASD Annual Meeting in Vienna.

Diamyd Medical will also present at the "The Life-Changing T1D Therapies INNODIA Symposium" on Monday September 15.

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 III trial with potential for an accelerated approval pathway in the US is actively recruiting patients with recent-onset (Stage 3) Type 1 Diabetes at 60 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 IIb 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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