CLOSER LOOK

MEMORANDUM

Diamyd Medical to accelerate primary efficacy readout of phase 3 DIAGNODE-3 trial in T1D by nine months – December 30, 2025

Following FDA Type C meeting, Diamyd Medical will accelerate the timepoint for the primary efficacy readout from 24 to 15 months; topline results expected data in March 2026

Diamyd Medical just announced that it will accelerate the primary efficacy readout of the phase 3 DIAGNODE-3 trial (n=330) of Diamyd in T1D by nine months. Following a Type C meeting[1], the FDA accepted the company's proposal to change the timepoint for the primary efficacy readout from 24 to 15 months. As a reminder, Diamyd is a GAD65 protein-containing molecule for people with detectable GAD65 antibodies and the HLA DR3-DQ2 haplotype, which affects about 40% of people with T1D.

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Topline results of phase 3 DIAGNODE-3 trial expected in three months

The phase 3 DIAGNODE-3 trial (n=330) is currently evaluating the efficacy and safety of Diamyd in patients recently diagnosed with T1D (within six months of diagnosis) who have the HLA DR3-DQ2 haplotype. Patients who wish to participate in the trial undergo an initial screening procedure to determine if they carry the specific genes and to assess their eligibility. The trial is only open to patients who have been recently diagnosed, as Diamyd aims to halt or delay the autoimmune attack on pancreatic beta cells. We're especially encouraged to see the trial's secondary endpoint, which includes CGM metrics, and hope that additional trials will integrate them into their studies.

The previously announced date for the topline results of the DIAGNODE-3 trial, including approximately 170 participants with 15-month data, remains on track for the end of March 2026. These results may support an accelerated Biologics License Application (BLA) pathway. The originally planned assessment for the 24-month period will serve as a secondary endpoint to evaluate the durability profile of Diamyd.

Previous results demonstrate the promising efficacy of Diamyd in T1D

Previously, at EASD 2025, Diamyd Medical announced a post-hoc meta-analysis (n=241) that highlighted the disease-modifying effect of Diamyd in people with stage 3 T1D. Results showed a dose-dependent benefit of Diamyd compared to placebo, with prolonged time above stimulated C-peptide >0.2 nmol/L and >0.5 nmol/L. These results suggest that Diamyd delays the progression of stage 3 quite significantly (about six months or longer, depending on thresholds), helping preserve beta cell function.

Additionally, in July 2024, Diamyd Medical announced positive interim analysis results from the DIAGNODE-3 trial. The interim analysis evaluated six-month data from 74 patients enrolled in the trial, determining the likelihood of achieving one of its co-primary endpoints: preservation of endogenous insulin, as measured by C-peptide level.

Diamyd Medical has received positive feedback from the FDA

Diamyd Medical has received several positive responses from the FDA during its journey to progress Diamyd as a

precision therapy for the treatment of T1D. For instance, Diamyd received two FDA Fast Track designations in February 2024 and July 2024 for people recently diagnosed with stage 3 T1D and pediatric populations with stage 1 or 2 T1D, respectively, who have the HLA DR3-DQ2 genotype. Additionally, in Diamyd Medical's 4Q24 update, the company stated that the FDA confirmed C-peptide levels as the primary endpoint for the trial, providing an expedited timeline for trial completion and regulatory filing.

Close Concerns' Questions

1. To what extent has C-peptide as a primary endpoint for the trial affected the approval of an accelerated trial readout?
2. What factors determine and influence the FDA's decision to adjust trial duration?
3. How does this announcement impact Diamyd Medical's plans to progress Diamyd for T1D? Does it affect any other trials the company is pursuing?

--by Esther Min, Monica Oxenreiter, and Kelly Close

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[1]Type C meetings refer to meetings between FDA and sponsors that are not Type A (meetings for products on clinical hold) or B (e.g., pre-IND, end-of-phase 1, end-of-phase 2 meetings).