Press release, April 21, 2025

Diamyd Medical highlights opportunity in Type 1 Diabetes prevention, adult-onset market, and upcoming Phase 3 readout

In a recent investor interview, Diamyd Medical Board Member Professor Mark Atkinson and CEO Ulf Hannelius shared key insights into the Company's positioning as a first-mover in precision medicine-based, disease-modifying and preventive treatment for Type 1 Diabetes. The discussion covered the strong safety profile and genetically targeted approach of the Diamyd Medical's investigational therapy Diamyd®, the opportunity to expand into the adult-onset autoimmune diabetes (LADA) segment increasingly recognized as part of the Type 1 Diabetes spectrum, and the major milestones ahead – including a registrational Phase 3 readout expected within 12 months.

"We are not just treating Type 1 Diabetes — we're actually aiming to prevent and cure it," says Ulf Hannelius, CEO of Diamyd Medical. "And with LADA now increasingly recognized as Type 1 Diabetes, the potential market more than doubles."

Positioning of Diamyd®
Diamyd® is a precision immunotherapy targeting individuals with a specific HLA genotype associated with Type 1 Diabetes. Over 1,000 patients have been treated with Diamyd®, a durable investigational antigen-specific GAD-based therapy, giving it a robust safety track record. The treatment aims to preserve endogenous insulin production by reprogramming the immune system—addressing the root cause of the disease rather than just managing blood glucose.

"Diamyd has one of the strongest safety profiles of any drug that I'm aware of seeking to prevent Type 1 Diabetes," says Professor Mark Atkinson, Board Member and Chair of Diamyd Medical's Scientific Advisory Board. "The combination of safety and therapeutic durability makes Diamyd a very attractive treatment."

A precision platform with broad reach
Diamyd Medical's approach is built around matching therapy to the patient's genetic profile. The Company is currently enrolling only patients with the appropriate HLA genotype in its Phase 3 trial DIAGNODE-3. Diamyd Medical is also taking steps to broaden its precision medicine platform.

"With GAD we target about 40 % of Type 1 Diabetics in the Western world. By adding insulin as a second antigen, we can potentially reach 90 %," says Ulf Hannelius. "This antigen-specific approach also makes Diamyd® an ideal candidate for future combination therapies—given its safety, durability and lack of systemic immune suppression."

"Some of the other candidates don't afford the ability for as a safe combination, because of toxicity or immune system compromise", says Professor Atkinson. "Given its strong safety profile and precision mechanism, I believe Diamyd has real potential as part of combination treatments."

Indications: From newly diagnosed to prevention and adult-onset Type 1 Diabetes
While Diamyd Medical's Phase 3 trial focuses on newly diagnosed Type 1 Diabetes (Stage 3), the Company's pipeline spans the full disease continuum — from at-risk individuals to slow-progressing adult-onset cases. Increasing scientific consensus now recognizes LADA (Latent Autoimmune Diabetes in Adults) as a form of Type 1 Diabetes.

"The American Diabetes Association now includes LADA under the Type 1 Diabetes umbrella," Ulf Hannelius emphasizes.

Professor Atkinson adds: “We now believe that it's just a population of slow-progressing individuals with Type 1 Diabetes that happen to occur in adults. Many of these patients are GAD antibody-positive, making Diamyd a unique and optimal drug.”

Diamyd Medical is one of the very few — and possibly the only — companies to have conducted interventional trials in LADA patients, with safety data extending up to age 70.

“If we secure regulatory approval in Type 1 Diabetes, we will explore extending our label to include adult-onset Type 1 Diabetes,” says Ulf Hannelius. “This could more than double the addressable market for Diamyd.”

Diamyd Medical has conducted market research in the United States that supports peak sales potential of USD 2 billion in the Stage 3 Type 1 Diabetes population targeted as the initial indication. The same research shows that extending the label to adult-onset Type 1 Diabetes could more than double the commercial opportunity.

Milestones ahead
Diamyd Medical expects several key milestones within the next 12 months including:

- Top-line results from its single pivotal Phase 3 trial DIAGNODE-3 to support an accelerated approval pathway in the U.S.
- GMP certification of its biologics manufacturing facility in Sweden

“DIAGNODE-3 is the first-ever precision medicine Phase 3 trial in Type 1 Diabetes,” says Ulf Hannelius. “We’ve screened over 600 patients to identify the right genetic match.”

“This trial is not a Hail Mary pass,” adds Professor Atkinson. “Countless months went into designing this trial based on past data, experience, and genetics. Everything pragmatically possible has been done to maximize the chances of success.”

A strong case for impact and market adoption
Beyond the scientific and regulatory readiness, the Company sees strong commercial potential.

“We’ve conducted market research in the U.S. with providers and payers,” Ulf Hannelius says. “The feedback has been very positive — they see a significant need and view this as a strong candidate for adoption.”

Professor Atkinson closes with a broader reflection:
“This is not just an investment opportunity. It’s a chance to improve lives, prevent disease, and be part of something that has real societal benefit.”

Watch the full 60-minute interview at: https://www.youtube.com/live/84cNuJVunHg?si=MYCjdbaEzoNyeuGK

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 is actively recruiting patients with recent-onset (Stage 3) Type 1 Diabetes at 60 clinics in eight European countries and in the US. An early read-out of the Phase 3 trial is expected in March 2026. 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 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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