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In-depth analysis of Diamyd® Phase II trial further supports value of preserved insulin secretion

An in-depth analysis of the continuous glucose monitoring data from the phase 2b trial DIAGNODE-2 with Diamyd® sheds new light on the importance of residual beta cell function in individuals recently diagnosed with Type 1 Diabetes. Most notably, the results show highly statistically significant and positive associations between residual beta cell function measured as stimulated C-peptide and reduction of the number and severity of hyperglycemic events, in other words episodes of high blood glucose levels, as well as improvements in glucose control during meal time. The results lend further support to the clinical relevance of therapeutically preserving C-peptide in Type 1 Diabetes, one of the two primary endpoints in the ongoing Phase 3 trial DIAGNODE-3.

“These results add valuable details to the evidence of how endogenous insulin production directly benefits individuals with recently diagnosed type 1 diabetes”, says Ulf Hannelius, CEO of Diamyd Medical. “Importantly, these insights are based on data from DIAGNODE-2, our own Phase 2b trial, representing the same patient population that is currently being addressed in our registrational precision medicine Phase 3 trial with Diamyd, DIAGNODE-3”.

The analysis

The updated analysis, performed in collaboration with the digital decision support company OneTwo Analytics (www.onetwo-analytics.com), dissects all the continuous glucose monitoring (CGM) data from DIAGNODE-2 into a large number of established and novel metrics describing glycemic control including mean glucose features, hyperglycemic features, hypoglycemic features and meal related features. These metrics convey information relevant to both the health and quality of life of the patient.

The preliminary results show a statistically highly significant positive association between residual beta cell function measured as stimulated C-peptide and several of these CGM metrics. The most substantial impact, with p-values below 0.0001, is seen on reducing the number and severity of hyperglycemic events, (episodes of high blood glucose levels), as well as improvements in glucose control during meal times for patients with recently diagnosed type 1 diabetes.

The results also show a significant protective effect of endogenous insulin production on several hypoglycemic measures, (episodes of below normal blood glucose levels). The preliminary analyses also provide more detailed support to the previously published effect of Diamyd® on improving glycemic control in individuals carrying the HLA DR3-DQ2 haplotype, emphasizing the importance of therapeutically preserving C-peptide.

Previously published on the value of C-peptide

As previously published in [Diabetes Care in 2021](#), a significant effect of Diamyd® in the Phase 2b trial DIAGNODE-2 on preserving endogenous insulin production measured as stimulated C-peptide was seen in the prespecified genetic subgroup of individuals that carried the HLA DR3-DQ2 haplotype. A follow-up publication published in [JCEM in 2022](#) showed a significant effect of Diamyd® on 1) improving time spent in the optimal glucose range (time in range, TIR), 2) reducing time spent in hyperglycemia (high blood glucose levels) and 3) reduced glucose fluctuations. Also, an updated meta-analysis published in [Diabetes, Obesity and Metabolism in 2022](#), based on the comprehensive data package comprising four placebo controlled clinical trials with Diamyd®, showed a clear correlation between preserved C-peptide and improved HbA1c, a measure of the average blood glucose levels over the span of 2-3 months.

The most comprehensive meta-analysis to date, recently published in [The Lancet Diabetes & Endocrinology in 2023](#), encompassing data from approximately 2,700 newly diagnosed type 1 diabetes patients who participated in 21 trials evaluating disease-modifying therapies including Diamyd®, underscores the significance of preserved C-peptide. The study's results indicated that preserving C-peptide in T1D patients led to a significant improvement in metabolic outcomes. The findings support the use of C-peptide as a surrogate endpoint in clinical trials and

confirm the potential of beta cell preserving interventions as effective adjuncts to insulin therapy in managing new-onset type 1 diabetes.

Beyond these findings on therapeutically preserved C-peptide that can be seen directly in clinical trials conducted on individuals with recent-onset T1D, there is also substantial evidence that preserved endogenous insulin production significantly reduce the incidence of diabetes-related complications such as diabetic ketoacidosis, severe hypoglycemia retinopathy, neuropathy, and nephropathy.

Continuous Glucose Monitoring

CGM technology, compared to traditional blood sugar testing methods, such as finger-pricking, offers real-time glucose level monitoring through a small, under-the-skin sensor. This sensor continuously tracks glucose concentrations, providing comprehensive data that is wirelessly transmitted to a receiver or a smartphone application. The continuous nature of this monitoring is invaluable in identifying glucose trends and patterns, enabling individuals with diabetes to make more informed decisions about diet, exercise, and medication in real time.

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for the prevention and treatment of Type 1 Diabetes and LADA (Latent Autoimmune Diabetes in Adults). Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruiting patients with recent-onset Type 1 Diabetes in eight European countries and in the US. Significant results have previously been shown in a large genetically predefined patient group - in a large-scale meta-analysis as well as in the Company's European Phase IIb trial, where Diamyd® was administered directly into a lymph node in children and young adults with recently diagnosed Type 1 Diabetes. A biomanufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65 protein, the active ingredient in the antigen-specific immunotherapy Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a component in treatments of metabolic diseases. Diamyd Medical is a major shareholder in the stem cell company NextCell Pharma AB as well as 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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