Press Release, April 12, 2024

Recruitment milestone reached in Diamyd® Phase 3 trial

Diamyd Medical's precision medicine Phase 3 trial for Type 1 Diabetes, DIAGNODE-3, has enrolled 100 patients. To date, no serious adverse events have been reported, and no patients have discontinued the trial.

"This is an important milestone in our Phase 3 trial and the notable zero dropout rate confirms our insights from previous trials regarding the safety and convinience of the treatment," says Ulf Hannelius, President & CEO of Diamyd Medical. "We are deeply grateful to our participants for their continued commitment to the trial and to the dedicated staff at our participating clinics for their relentless efforts."

DIAGNODE-3, being the first ever precision medicine Phase 3 trial in type 1 diabetes, is ongoing in eight European countries and in the United States. The trial specifically enrols patients that carry the genetic HLA DR3-DQ2 haplotype, a genetic subgroup of type 1 diabetes that in previous trials has been associated with positive clinical response to Diamyd® treatment. The antigen-specific immunotherapy Diamyd® was in February 2024 granted Fast Track designation by the FDA and has previously been granted Orphan Drug designation in the U.S.

About DIAGNODE-3
The confirmatory Phase III trial DIAGNODE-3 (www.diagnode-3.com), evaluating the safety and efficacy of the antigen-specific immunotherapy Diamyd® in individuals diagnosed with Type 1 Diabetes is ongoing in the United States and in eight European countries: Sweden, Spain, the Czech Republic, the Netherlands, Germany, Poland, Hungary and Estonia.
DIAGNODE-3 will enroll up to 330 individuals aged 12 to 29 years, recently diagnosed (within 6 months) with Type 1 Diabetes, who carry the HLA DR3-DQ2 haplotype, a certain genetic risk factor for Type 1 Diabetes. A further stratification for HLA haplotypes is included in order to evaluate the potential super responder group of individuals who are positive for HLA DR3-DQ2 and negative for HLA DR4-DQ8. HLA testing is well established and widely available.

This patient population is based on clinical efficacy and safety results from the Phase IIa and Phase IIb trials DIAGNODE-1 and DIAGNODE-2, as well as on the large-scale meta-analysis encompassing data from more than 600 individuals from previous Phase II and Phase III trials using Diamyd®. The trial design provides a high probability to reach its co-primary endpoints of preservation of endogenous insulin producing capacity measured as stimulated C-peptide and improved blood glucose control as determined by HbA1c.

DIAGNODE-3 is supported in part by funding from JDRF, the leading global type 1 diabetes research and advocacy organization.

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 immunomodulatory therapeutic for the preservation of endogenous insulin production that has been granted Orphan Drug Designation in the U.S. as well as Fast Track Designation (Feb-2024) by the U.S. FDA. 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 prospective European Phase IIb trial, where Diamyd® was administered directly into a superficial lymph node in children and young adults with recently diagnosed Type 1 Diabetes. Injections into a superficial lymphnode can be performed in minutes and is intended to optimize the immune response. 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 also develops the GABA-based investigational drug Remygen® as a component in the 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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