Press release, November 5, 2024

Diamyd Medical and INNODIA partner for Type 1 Diabetes awareness and patient recruitment for the DIAGNODE-3 precision medicine trial

Diamyd Medical has entered a strategic partnership with INNODIA, an international non-profit organization dedicated to advancing research on disease modifying therapies for Type 1 Diabetes. The partnership will leverage INNODIA's extensive EU-based clinical network with the aim to further amplify patient enrolment and the visibility of the precision medicine Phase 3 trial DIAGNODE-3 ahead of a potential accelerated Biologics Licensing Application in the U.S.

"We are delighted to work with INNODIA to spread the awareness of Type 1 Diabetes and Diamyd®, as well as to ensure that we meet critical recruitment milestones in DIAGNODE-3 ahead of a potential BLA under the Accelerated Approval Program," says Ulf Hannelius, CEO of Diamyd Medical. "This partnership enhances our ability to bring Diamyd® to market, potentially as a first-in-class precision treatment for Stage 3 Type 1 Diabetes."

"By joining forces with Diamyd Medical, we are advancing our shared mission of improving lives for persons with Type 1 Diabetes," says Manuela Battaglia, Managing Director of INNODIA. "INNODIA's network will be instrumental in reaching patients across Europe, contributing to this transformative effort."

About DIAGNODE-3
The confirmatory Phase 3 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 enrol 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 2a and Phase 2b 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 2 and Phase 3 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 Breakthrough T1D (formerly JDRF), the leading global Type 1 Diabetes research and advocacy organization.

About INNODIA
INNODIA is an international non-profit organization dedicated to accelerating the development of preventive and curative therapies for Type 1 Diabetes (T1D). INNODIA's mission is to empower medicine developers with the tools and services they need to effectively halt T1D. INNODIA's services are delivered through a dynamic network of academic institutions specializing in T1D research and treatment (INNODIA Members). This vibrant network is further strengthened by the INNODIA People Living with Type 1 Diabetes Community (INPACT), a large group of individuals trained and empowered through dedicated programs to support INNODIA's mission. INNODIA also sponsors a T1D screening program, aimed at identifying individuals at stage 1 and 2 of T1D across all INNODIA clinical sites. This initiative provides immediate opportunities for these individuals to participate in preventive clinical trials. The value of INNODIA lies in its mission-driven impact; INNODIA's only 'shareholders' are people with T1D, whose lives and well-being guide INNODIA's purpose.

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 by the U.S. FDA for the treatment of Stage 1, 2 and 3 Type 1 Diabetes. DIAGNODE-3, a confirmatory Phase 3 trial is actively recruiting patients with recent-onset (Stage 3) 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 2b 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 are intended to optimize the treatment 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 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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