Press Release, February 15, 2024

Diamyd Medical receives U.S. FDA Fast Track designation for Diamyd®

Diamyd Medical announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for Diamyd® (rhGAD65/alum) that is being investigated to improve glycemic control in recently diagnosed stage 3 Type 1 Diabetes patients with the genotype HLA DR3-DQ2. The FDA grants Fast Track designation to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need. Fast Track designation is intended to bring promising medicines to patients sooner.

"We are very pleased with the FDA's decision to grant Fast Track designation for Diamyd and the potential this provides to accelerate Diamyd's path to entering the US market", says Ulf Hannelius, CEO of Diamyd Medical. "Type 1 diabetes is a progressive, chronic and irreversible autoimmune disease that affects millions of patients worldwide. Diamyd, currently evaluated in the first ever precision medicine Phase 3 trial in type 1 diabetes, DIAGNODE-3, represents a significant shift towards personalized medicine in the treatment of type 1 diabetes. This offers new hope beyond the traditional insulin therapy, emphasizing our dedication to advancing care and improving outcomes for patients."

The treatment paradigm for Type 1 Diabetes is shifting towards precision medicine, due to inadequacy of current treatment options that are characterized by a failure to consistently achieve glycemic targets as well as the prevalence of short- and and long-term complications. This highlights the urgent need for new therapeutic approaches like the antigen-specific therapy Diamyd® that has shown promising results in preserving pancreatic beta cell function and improving glycemic control in individuals with Type 1 Diabetes. In clinical trials, Diamyd® has demonstrated the potential to specifically and safely modulate the immune system's response against pancreatic beta cells, aiming to halt or slow the disease's progression. Diamyd® is currently being evaluated in the first-ever precision medicine Phase III trial, DIAGNODE-3, in individuals recently diagnosed with Type 1 Diabetes carrying the HLA DR3-DQ2 genotype.

For further information regarding Fast Track drug development programs, please refer to the guidance for industry Expedited Programs for Serious Conditions – Drugs and Biologics at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf.

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.

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 that has Orphan Drug Designation in the U.S. and in February 2024

was granted Fast Track designation by the U.S. FDA. DIAGNODE-3, a confirmatory Phase III trial is actively recruting 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 superficial lymph node in children and young adults with recently diagnosed Type 1 Diabetes. Injections in to a superficial lymphnode can be performed in minutes and is intended to optimize the immune response. A biomanufacturing facility 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.

For further information, please contact:
Ulf Hannelius, President and CEO
Phone: +46 736 35 42 41
E-mail: ulf.hannelius@diamyd.com

Diamyd Medical AB (publ)
Box 7349, SE-103 90 Stockholm, Sweden. Phone: +46 8 661 00 26, Fax: +46 8 661 63 68
E-mail: info@diamyd.com Reg. no.: 556242-3797 Website: https://www.diamyd.com

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