Press Release, December 6, 2023

# Diamyd Medical's Precision Medicine patent for the prevention and treatment of autoimmune diabetes granted in South Korea

*The patent, granted by the South Korean Patent Office and valid until 2035, safeguards the application of GAD autoantigen in treating or preventing autoimmune diabetes, specifically in individuals with the HLA DR3-DQ2 gene. GAD, the key component in Diamyd®, an antigen-specific immunotherapy, currently under evaluation in the registrational Phase III trial DIAGNODE-3. This trial is recruiting patients with recent-onset Type 1 Diabetes across eight European countries and the US.*

HLA DR3-DQ2 is a genetic marker linked to Type 1 Diabetes, found in up to 40% of those with the disease. The specificc HLA-type is associated with an autoimmune response against the protein GAD. A large-scale analysis (published 2020 in Diabetologia) showed that individuals with HLA DR3-DQ2 responded well to Diamyd®. This finding was further confirmed in the Phase IIb DIAGNODE-2 trial (published 2021 in Diabetes Care). Additional research (published 2022 in Diabetes, Obesity & Metabolism and The Journal of Clinical Endocrinology & Metabolism) further supported Diamyd®'s efficacy and clinical significance of therapeutically preserving natural insulin production,. These findings have lead to the design and launch of the precision medicine Phase III trial DIAGNODE-3 (trial design published 2022 in BMJ Open) currently recruiting patients in Europe and the US.

Besides South Korea, the precision medicine patent for this treatment has also been granted in Europe and Eurasia, with applications pending in other countries. Diamyd Medical has exclusive license rights from UCLA to a substance of matter patent in the United States, valid until 2032 for treating diabetes with GAD. Additionally, patents valid until 2035 cover the intralymphatic administration of Diamyd® in Australia, Canada, China, Europe, Israel, Japan, and Russia, with more countries pending. This administration method is the one used in the ongoing DIAGNODE-3 trial. Independently of patent protection, Diamyd® will receive market exclusivity for 12 years in the US and 10 years in Europe from the date of market approval, owing to its status as a biological drug. It has also been awarded orphan designation in the US which provides 7 years of market exclusivity and certain development incentives.

**About Diamyd Medical**
Diamyd Medical develops precision medicine therapies for Type 1 Diabetes. Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. 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 DIAGNODE-2, 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, the active ingredient in the antigen-specific immunotherapy Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. Diamyd Medical is one of the major shareholders 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

The information was provided by the contact person above, for publication on December 6, 2023, 14.50 CET.