Press Release, June 30, 2022

Diamyd Medical joins international consortium in Type 1 Diabetes

Diamyd Medical will be a full voting member of the Type 1 Diabetes Consortium (T1DC) led by the US non-profit organization the Critical Path Institute (C-Path). The T1DC brings together diverse stakeholders from industry, academia and patient organizations to develop solutions to accelerate drug development for Type 1 Diabetes, including biomarker endpoints and model-informed drug development tools in close collaboration with regulatory agencies to enable easier and faster regulatory approval of new treatments.

By creating a unique assembly of data from previous prevention and intervention trials in Type 1 diabetes, including trials conducted with the therapeutic diabetes vaccine Diamyd®, T1DC aims to optimize the planning and conduct of clinical trials by developing novel solutions including clinical trial simulation tools and by providing regulatory agencies with robust data for the acceptance of biomarkers as endpoints in clinical trials (https://c-path.org/programs/t1d/).

"For us, as a full voting member of T1DC, this is not only an important opportunity to be at the forefront of a changing regulatory landscape, but our contribution of data from previous trials also underlines the robustness of the evidence underpinning the safety and efficacy of our diabetes vaccine," said Ulf Hannelius, President and CEO of Diamyd Medical. "Improvements in regulatory solutions achieved by the T1DC may ultimately lead to a faster and less recourse-demanding way to the market with direct relevance for planned and ongoing trials with the diabetes vaccine Diamyd."

"T1D poses a considerable burden to patients' lives. New and better therapies that improve the lives of those at risk or living with T1D are desperately needed," said C-Path T1DC Executive Director Elnaz Atabakhsh, Ph.D. "The T1D Consortium works to accelerate the process to develop these therapies, a goal that can only be achieved through rich collaboration between scientists, clinicians, patients, regulators and key industry members, such as Diamyd Medical. The data and expertise Diamyd Medical has shared with C-Path has been invaluable and we are thrilled for Diamyd Medical to join as members of the T1D Consortium."

Diamyd Medical contributes to T1DC with data from previous Diamyd® clinical trials and will become an active voting participant in determining the consortium's focus and aims. Of particular interest for Diamyd Medical will be the advancement of C-peptide preservation (a biomarker for the body's own insulin production) as a primary endpoint for regulatory approval. Another focus for Diamyd Medical will include developing Continuous Glucose Monitoring (CGM) as an endpoint fit for regulatory approval. As previously communicated and detailed in several peer-reviewed scientific articles, Diamyd® achieves robust statistically and clinically meaningul effects compared to placebo treamtent in both of these endpoints.

About Critical Path Institute
Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and hundreds of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona, C-Path in Europe is headquartered in Amsterdam, Netherlands and C-Path Ltd. operates from Dublin, Ireland with additional staff in multiple other locations. For more information, visit https://c-path.org/

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About Diamyd Medical
Diamyd Medical develops precision medicine therapies for Type 1 Diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have 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 the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. DIAGNODE-3, a confirmatory Phase III trial is on-going. A vaccine manufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine 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. An investigator-initiated Remygen® trial in individuals living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. 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; phone: +46 8-528 00 399, e-mail: info@fnca.se

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