



Press Release, October 12, 2020

Financial and operational update about the diabetes vaccine Diamyd®

Diamyd Medical's current cash position of approximately SEK 180 million supports all ongoing operational activities for the financial year as well as start-up activities for a confirmatory phase III trial with the diabetes vaccine Diamyd® in both the United States and Europe that is currently being planned. The Company is also pursuing potential partnerships for future commercialization alongside discussions with potential investors, with the aim of fully financing the execution of the phase III program, the manufacturing program, and market launch as well as to facilitate pivotal development programs for prevention of type 1 diabetes and treatment of Latent Autoimmune Diabetes in Adults (LADA).

Diamyd Medical will discuss the phase III program with the FDA Q1 2021. The final design will then be finalized and a global clinical research organization will in parallel be signed to start the operational activities. This trial will be designed to consider both the primary endpoint of preserving endogenous insulin production as well as key secondary endpoints focusing on disease management. This effort will confirm and expand on the efficacy and safety of Diamyd® based on previous phase I, II and III trials in individuals recently diagnosed with type 1 diabetes. Specifically, the trial will focus on the genetically defined patient group identified in previous trials in order to only include individuals that have a high likelihood of benefiting from the treatment. This precision medicine based approach is a way to individualize medications as has been used with great success in emerging treatments for cancer.

The genetically defined patient group most likely to see therapeutic benefit consists of individuals positive for the HLA-type DR3-DQ2, represents up to 50% of all individuals diagnosed with type 1 diabetes. Overall, for individuals aged 0-64 years, the number of annual incident cases of type 1 diabetes in the United States was for 2015 estimated to be 64,000 (Rogers et al, BMC Medicine, Vol 15, 2017).

In parallel with the clinical development efforts, the establishing of the vaccine manufacturing facility in Umeå, Sweden, is progressing. The primary purpose of the facility is to provide full control and predictability of the manufacturing of the active ingredient in Diamyd®, the recombinant protein GAD65, ahead of commercialization. Several PhD level key positions have been filled in Umeå including the Site Manager, Maja Johansson, PhD, Associate Professor; Production Scientists and a Quality Manager. For more on the Umeå facility, see a recent interview with Maja Johansson, (<https://www.ubi.se/news/diamyd-medical-moves-pharmaceutical-production-from-usa-to-umea-hires/>).

The Company has also recently employed a Regulatory Affairs Officer to further enhance the regulatory strategy work for the diabetes vaccine, including pricing strategy and manufacturing.

About type 1 diabetes and disease modifying therapies

Type 1 diabetes is an autoimmune disease where the insulin producing beta cells in the pancreas are destroyed by the immune system. There is currently no cure or disease-modifying therapies for type 1 diabetes. Despite the availability of insulin, the disease is associated with serious short and long term complications, such as acute low blood sugar (hypoglycaemia), cardiovascular problems as well as kidney and nerve damage leading to great human suffering and high costs to society.

At diagnosis, most patients still possess a small amount of insulin producing capacity, as assessed by serum C-peptide levels. The more endogenous insulin producing capacity a patient retains, the less likely the patient is to suffer from short- and long-term complications. New therapies are needed that will retain or improve residual beta cell function, which would in turn lead to improved glycemic control and a lower risk of developing debilitating complications.

To this fact, a concept white paper "Modeling the Total Economic Value of Novel Type 1 Diabetes (T1D) Therapeutic Concepts", released in February 2020, spotlights the high economic burden of type 1 diabetes and the

immense value of accelerating disease-modifying therapies. The white paper can be downloaded here: <https://t1dfund.org/wp-content/uploads/2020/02/Health-Advances-T1D-Concept-Value-White-Paper-2020.pdf>

About Diamyd Medical

Diamyd Medical develops 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 genetically predefined patient group in a large-scale metastudy as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes. A new facility for vaccine manufacturing 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 patients 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.

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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