



Press release, November 15, 2018

Diamyd Medical updates on the Company and the diabetes vaccine Diamyd® ahead of the Annual General Meeting today

At today's Annual General Meeting, CEO Ulf Hannelius presents the latest developments with the diabetes vaccine Diamyd®. Presentations will be held by Professor Per-Ola Carlsson, Uppsala University Hospital and Uppsala University and Professor Johnny Ludvigsson, Linköping University. Professor Mark A. Atkinson, University of Florida, USA, who is joining the Company's Board of Directors, will participate via video link. The meeting will be held at 5:00 pm CET in Stockholm.

Diamyd Medical's main focus with regard to the diabetes vaccine Diamyd® is to increase the international awareness about the Company's progress, to complete the European trial DIAGNODE-2 and prepare for market. Within this framework, Professor Mark A. Atkinson, University of Florida, USA, one of the world's leading authorities in type 1 diabetes, is proposed to join the company's Board of Directors.

75 patients of a total of 106 have so far been included in DIAGNODE-2 and the aim is to have the trial fully recruited during the first quarter of 2019. Together with Spain, the Czech Republic and Sweden, the Netherlands becomes the fourth country where the trial is conducted, as a clinic in Rotterdam, which also participated in the Company's previous Phase III program, is opened to ensure a continued good recruitment rate.

In the DIAGNODE-1 pilot trial, the three patients that were offered a fourth so-called booster injection of intralymphatic Diamyd® have completed the treatment without any serious side effects. The clinical and immunological results of these three participants will be followed up during next spring. Diamyd Medical has previously informed of positive clinical and immunological results for all 12 patients who have been followed for 15 months. 30-month results for all patients are expected around the turn of the year 2019/2020. The trial may be monitored earlier, prior to important partner meetings or conferences.

Market preparation activities are also underway regarding the manufacturing of the protein GAD (glutamic acid decarboxylase) and the formulation of Diamyd® study drug. As previously announced, manufacturing of new GAD batches for use in late stage clinical trials and potential early market launch in newly diagnosed type 1 diabetes is planned to coincide with the results from DIAGNODE-2. In addition, fully formulated study drug is in place with a shelf life until 2021. In order to strengthen the negotiating position for partner agreements, evaluation of the manufacturing process and the possibility of initiating additional manufacturing sites is ongoing. The goal is that the manufacturing capacity should be aligned with a comprehensive international market launch, taking into account the possible expansion to the LADA indication (Latent Autoimmune Diabetes in Adults) and disease prevention.

Cash at hand amounted to SEK 35 million on November 14. At full utilization rate of all outstanding warrants during the current subscription period, Diamyd Medical will receive approximately SEK 61 million before issue costs. Two warrants in Diamyd Medical entitle the holder to subscribe for a new share at the price of SEK 4.55. The closing price as of November 14 for Diamyd Medical's B-share was SEK 6.01. Warrants can be traded on Nasdaq First North until November 28.

About the diabetes vaccine Diamyd® compared to other technologies

Diamyd® is the furthest developed antigen-specific immunotherapy in the world for autoimmune diabetes. Diamyd® is also the only therapy based on the GAD65 protein, the antigen that patients diagnosed with type 1 diabetes and LADA most often have antibodies against. Many other immunotherapies are based on peptides, ie shorter parts of, for example, insulin proteins, while Diamyd® contains the entire GAD65 as the active component. This means that the whole protein is treated naturally by the body's immune cells without the drug manufacturer having made assumptions about which part of the protein that is most important.

About Diamyd Medical

Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in trials with more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company's own European Phase-II trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymph node, there are four investigator initiated clinical trials ongoing with Diamyd®. Diamyd Medical also develops Remygen®, an oral GABA-based investigational drug. An investigator-initiated trial in patients with type 1 diabetes since at least five years has started at Uppsala University Hospital. An investigator-initiated placebo-controlled trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is ongoing at the University of Alabama at Birmingham. Exclusive licenses for GABA and positive allosteric modulators of GABA receptors for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine Diamyd® and Remygen® key assets. Diamyd Medical is also one of the major shareholders in the stem cell company NextCell Pharma AB and has holdings in the medtech company Companion Medical, Inc., San Diego, USA and in the gene therapy company Periphagen, Inc., Pittsburgh, USA.

Diamyd Medical's B-share is traded on Nasdaq First North under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

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