Press release, September 18, 2018

Diamyd Medical clarifies the goal of applying for earlier market approval for Diamyd®

Diamyd Medical's goal is to submit a marketing application for the diabetes vaccine Diamyd® late 2020. Diamyd Medical also announces that immunological results from all patients in DIAGNODE-1 will be presented this autumn.

Due to a large unmet need for therapies that preserve the endogenous insulin production in new-onset type 1 diabetes, Diamyd Medical's assessment is that DIAGNODE-2, with positive results and an advantageous safety profile, may form the basis for an earlier market approval, with the aim of submitting a market application in late 2020. This assumes that results from the extended DIAGNODE-2 trial will be in the third quarter of 2020, and that the market application is submitted in the fourth quarter of the same year.

In parallel with recruitment activities for DIAGNODE-2, immunological analyses are ongoing in DIAGNODE-1. The aim of the analysis is to confirm and clarify previously published and patent pending findings, where it has been observed that intralymatic administration of Diamyd® gives rise to a stronger and more sustainable immunological modification compared to subcutaneous (under the skin) administration. Results from the immunological analyses are expected to be available this fall.

The recently announced results from DIAGNODE-1 have also strengthened a patent application based on how patients with certain genes associated with autoimmunity in type 1 diabetes respond to the diabetes vaccine Diamyd®.

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 studies 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 study drug which in June 2018 was approved by the Swedish Medical Agency for clinical trial. 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.

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)
Kungsgatan 29, SE-111 56 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