Press release, August 27, 2019

Timeline update on GABA/Diamyd® and Remygen® clinical trials

Preliminary findings and study details of the GABA/Diamyd® trial conducted in the US will be presented by Professor Kenneth McCormick, Principal Investigator and Sponsor, on September 17, 2019 at the Annual Meeting of the European Association for the Study of Diabetes (EASD), in Barcelona, Spain. Final results, including immunological findings and subgroup analyses, are expected later this year and in early 2020.

The dose-escalation part of ReGenerate-1, evaluating the safety, pharmacokinetic properties and short-term metabolic effect of Remygen® is expected to be finalized this autumn. The second part of the trial, evaluating the long-term effect of Remygen® alone and in combination with the GABA receptor modulator Alprazolam, is expected to start recruiting patients later this year.

About the GABA/Diamyd® trial
GABA/Diamyd® is a three-arm, double-blind and placebo-controlled trial including a total of 101 children and adolescents between 4 and 18 years, recently diagnosed with type 1 diabetes. The patients have been randomly assigned to one of three treatment groups: a) two injections of Diamyd® (administrated subcutaneously) in combination with daily oral treatment with GABA, b) GABA only, or c) placebo. Patients have been followed for 12 months after which the effect on the preservation of the endogenous insulin production is analyzed. The trial has been conducted in the United States and led by Professor Kenneth McCormick at University of Alabama at Birmingham, Principal Investigator and Sponsor of the trial. Dr. McCormick treats patients at Children's of Alabama.

About the ReGenerate-1 trial
ReGenerate-1 is an open, investigator initiated clinical trial involving a total of about 36 patients aged 18-50 who have had type 1 diabetes for more than five years and have low to non-residual insulin production. The trial is conducted at the Uppsala University Hospital with Professor Per-Ola Carlsson as Principal Investigator. The trial consists of two parts; an initial safety and dose escalation section comprising six patients, and the main trial, which comprises 36 patients who will be followed up to nine months depending on the dose group to which they belong. The main purpose is to evaluate the safety of Remygen®, Diamyd Medical's own formulation of GABA, and the combination of Remygen® and Alprazolam. The trial will also examine whether Remygen® alone and in combination with Alprazolam can restore beta cell function, and in the long run allow a patient to regain insulin producing ability.

About Diamyd Medical
Diamyd Medical develops the diabetes vaccine Diamyd®, as an antigen-specific immunotherapy for the preservation of endogenous insulin production. Diamyd® has demonstrated good safety in trials encompassing more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company's own European Phase IIb trial DIAGNODE-2 where the diabetes vaccine is administered directly into a lymph node, two investigator initiated clinical trials are ongoing with Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® for regeneration of endogenous insulin production. 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 and has holdings in the medtech company Companion Medical, Inc., San Diego, 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; phone: +46 8-528 00 399, e-mail: info@fnca.se

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

The information was submitted for publication, through the agency of the contact person set out above, at 11.40 CET on August 27, 2019.