Press release, March 26, 2019

Diamyd Medical announces strategic activities for 2019 and 2020

With experience from clinical trials in more than 1,000 patients with the diabetes vaccine Diamyd®, preparations for a Conditional Marketing Authorization Application in Europe end of 2020 are underway. This includes regulatory, manufacturing and commercial activities as well as preparations for a Phase III clinical trial in Europe and the US, to be completed post-approval in support of an accelerated approval process.

"As seen in the DIAGNODE-1 trial, where 11 out of 12 patients remain in Partial Remission at 15 months, it seems that our intra-lymphatic injections of Diamyd® finally may lead us to success," says Ulf Hannelius, CEO of Diamyd Medical. "We have one of the most promising late-stage therapeutics for type 1 diabetes and LADA in the world. Together with our other assets and investments we have a solid foundation to prepare for future growth and success in the diabetes field."

Existing resources will be used primarily for finalizing the European Phase IIb trial DIAGNODE-2 as well as selected regulatory and commercial activities. Additional activities including the launch of a Phase III trial end of 2020 as well as manufacturing for commercial supply are outside current funds, and will be financed through future partnerships and/or institutional investors, which may include a main market listing.

Meetings with the European Medicine Agency (EMA) and the US Food and Drug Administration (FDA) regarding the development program and accelerated approval processes are being planned for 2019 and 2020. Market preparatory activities will also include commercial analyses, market access and pricing strategies. In parallell, and as part of accelerated approval process, a Phase III clinical trial in Europe and the US to be completed post-approval is being planned. The aim is to start the trial in conjunction with applying for Conditional Marketing Authorization in Europe end of 2020.

About Conditional Marketing Authorization
Conditional Marketing Authorization is an early-access pathway in Europe that supports the development of medicines that address unmet medical needs of patients. In the interest of public health, applicants may be granted a conditional marketing authorisation for such medicines where the benefit of immediate availability outweighs the risk of less comprehensive data than normally required, based on the scope and criteria defined in legislation and guidelines.

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, four 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. An investigator-initiated trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is also ongoing at the University of Alabama at Birmingham, USA. 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

This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08.17 CET on March 26, 2019.