Press release, March 8, 2019

European Phase IIb trial in type 1 diabetes with the diabetes vaccine Diamyd® close to being fully recruited

91 out of a total of 106 patients with type 1 diabetes are included in the European phase IIb trial DIAGNODE-2, where the diabetes vaccine Diamyd® is given directly into the lymph node with the aim to preserve the patients' endogenous insulin production. As previously announced, results from the trial are expected during the third quarter of 2020.

The Phase IIb trial DIAGNODE-2 is a follow up trial based on a smaller investigator initiated pilot trial, DIAGNODE-1, where results show that 11 out of 12 patients recently diagnosed with type 1 diabetes are in a so called honeymoon period, also called partial remission, 15 months after the start of the trial. Partial remission in type 1 diabetes is characterized by low external insulin requirement and near to normal long-term blood sugar levels. The results also show effect on preserving the patients' endogenous insulin production, measured as stimulated C-peptid. By maintaining the endogenous insulin production there is a potential to make a significant difference in the daily life of patients as well as to reduce the complications of type 1 diabetes.

"We have high expectations on DIAGNODE-2 given the very promising 15-month results from the pilot trial DIAGNODE-1", says Ulf Hannelius, CEO of Diamyd Medical. "Final screening activities are ongoing to wrap up patient enrollment during the spring."

About type 1 diabetes
Type 1 diabetes is an autoimmune disease where the beta cells, the cells in the pancreas that produce insulin, are destroyed by the immune system. GAD65 (glutamic acid decarboxylase) is an endogenous protein that is expressed by the beta cells. In type 1 diabetes, the immune system identifies the protein as dangerous and attacks and destroys the insulin-producing cells. GAD65 is the active ingredient in the diabetes vaccine Diamyd® which is being developed with the aim to reduce the immune system's sensitivity to GAD65 and thus preserving the remaining insulin production.

About partial remission
After diagnosis and commencement of exogenous insulin therapy, most patients enter into a so called honeymoon period or partial remission, characterized by low need for exogenous insulin due to improved insulin sensitivity and/or endogenous secretion, while long-term blood sugar (HbA1c) is maintained at near to normal levels. Development of immunomodulatory therapies that downregulate the inflammation in pancreatic islet cells and support the function and regeneration of insulin producing beta cells are considered of greatest importance for the prolongation of this partial remission period.

About DIAGNODE-2
The placebo-controlled trial DIAGNODE-2 encompasses approximately 106 patients from Spain, the Czech Republic, Sweden and the Netherlands, aged 12–24 years. The patients, recently diagnosed with type 1 diabetes are given the diabetes vaccine Diamyd® (or its placebo) directly into the lymph node on three occasions, one month apart, in combination with oral vitamin D (or its placebo) during four months, starting 30 days prior to the first injection. The patients are followed for 15 months with the aim to evaluate the remaining insulin producing capacity. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University. Sponsor for the trial is Diamyd Medical.

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; 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

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