Press release, September 9, 2019

Feasibility study supports the use of intralymphatic injections of Diamyd®

A feasibility study performed as a Master Thesis at Uppsala University and supervised by Diamyd Medical, supports the use of ultrasound guided intralymphatic injections for clinical routine use. This pilot study is based on interviews with and answers to questionnaires from selected radiologists and answers to questionnaires from selected study nurses participating in the ongoing DIAGNODE-2 trial where the antigen-specific immunotherapy Diamyd® is administered directly into a lymph node.

The insights from the study are in line with previous conclusions regarding the feasibility of intralymphatic injections such as in the treatment of allergy. The procedure is considered simple and safe to perform and is associated with very little discomfort for the patient. The study also shows that portable ultrasound devices can be used to guide the injections, giving support for performing the procedure outside of specialized radiology departments.

"This study provides added support that intralymphatic immunotherapy with Diamyd® is fully feasible and that the treatment can be made available also to patients not having access to to specilized hospitals," says Ulf Hannelius, CEO of Diamyd Medical. "This is important as we want to make sure that Diamyd®, if market approved, can benefit as many patients as possible."

The Master Thesis by Selam Fessehaye titled "Evaluation of the Feasibility of Intralymphatic Injection of Diamyd®" can be accessed at http://urn.kb.se/resolve?urn=urn%3Anbn%3Ase%3Auu%3Adiva-389630.

About DIAGNODE-2
The placebo-controlled trial DIAGNODE-2 encompasses 109 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. For more information about the trial, see www.diagnode-2.com.

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 Growth Market 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

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