Press release, August 21, 2018

Strategic expansion of Diamyd Medical's European Phase II trial in Type 1 diabetes

This is a resubmission of the earlier press release on August 21, 2018, in which it was incorrectly referred to the Market Abuse Regulation.

The Swedish Medical Products Agency has approved an expansion of DIAGNODE-2, the Phase II trial where the diabetes vaccine Diamyd® is administered directly into the lymph node, to comprise a total of approximately 106 patients. The expansion, which is awaiting approval in Spain and the Czech Republic, is being made to increase the trial's statistical power and weight in the development of the antigen-specific intralymphatic immunotherapy Diamyd® for Type 1 diabetes.

The application for amendment to allow recruitment of approximately 26 more patients to a total of 106 participants, has been submitted to the Competent Authorities in Sweden, Spain and the Czech Republic. To support the recruitment of the additional patients, work is ongoing to increase the number of participating clinics by opening for patient recruitment in a fourth European country.

By August 21, 75% of the patients, or 60 out of the initial total of 80 patients, had been included in the trial.

"The recruitment of patients to the trial is proceeding well and we are pleased with the approval by the MPA to expand the trial, says Ulf Hannelius, CEO of Diamyd Medical. "The higher number of patients strengthens the trial, which is strategically valuable for our clinical work and business development".

About DIAGNODE-2
The placebo-controlled trial DIAGNODE-2 encompasses after expansion approximately 106 patients from Spain, the Czech Republic and Sweden, 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 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.

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