



Press release, September 21

Phase II trial DIAGNODE-2 with the diabetes vaccine Diamyd® approved to start in all participating countries

Spanish and Czech Competent Authorities and the relevant Ethics Committees have approved Diamyd Medical's application to conduct DIAGNODE-2, a pivotal follow-up placebo-controlled Phase II trial with the diabetes vaccine Diamyd® to be tested in children and young adults recently diagnosed type 1 diabetes. Previously, the trial has been approved by the Swedish Medical Products Agency and the Ethics Committee.

Contract writing with all participating clinics, packing and blinding of study drugs and validation of systems and processes to be used in the trial scheduled for the autumn, is ongoing. Trial details and processes will be presented to investigators and nurses from participating clinics at the Investigators meeting, which will be held by Diamyd Medical in Barcelona, Spain, on 5-6 October.

About DIAGNODE-2

DIAGNODE-2 is based on the ongoing open label pilot trial DIAGNODE-1, where preliminary results show a positive clinical progression and desired immunological response as the diabetes vaccine Diamyd® is given directly into the lymph node. DIAGNODE-2 will include approximately 80 patients from Spain, the Czech Republic and Sweden aged 12-24 years, recently diagnosed with type 1 diabetes. The patients will be followed for 15 months with the aim to evaluate the remaining insulin producing capacity. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University.

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. Four clinical trials are ongoing with Diamyd®. The Company's trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymph node, is expected to start recruiting patients in the fall. An exclusive license for GABA for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine a key asset in Diamyd Medical and the Company uses its GABA in-licensed technology to develop a GABA drug product. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB. Diamyd Medical also 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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