



Press release, May 18, 2018

### **Update regarding the manufacturing of Diamyd® drug substance**

Diamyd Medical and the Company's manufacturer of recombinant GAD, the active component of the diabetes vaccine Diamyd®, are working on an updated plan for the new batches of GAD that Diamyd Medical ordered last year for use in late clinical trials and possible early market launch. Manufacturing of the new batches will according to the updated plan be finalized within a time frame that coincides with results from the DIAGNODE-2 trial, which also optimizes the shelf life of the drug substance.

#### **About DIAGNODE-2**

The placebo-controlled trial DIAGNODE-2 encompasses approximately 80 patients aged 12–24 years, from Spain, the Czech Republic and Sweden. 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). 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. 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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