



Press release, March 2, 2018

## **Operational update on the diabetes vaccine Diamyd® and recombinant GAD**

*Diamyd Medical hereby provides an update on its operations, including the intralymphatic trials with Diamyd® and the GAD production.*

### **Clinical trials with intralymphatic administration of Diamyd®**

As previously announced, there is a great interest in the DIAGNODE-2 trial, where the diabetes vaccine Diamyd® is administered directly into the lymph node, and it is further increasing, according to recent information from the clinics. As of March 1, 33 patients had been evaluated (screened) if they could be included in the trial, of which 24 were screened in February only. The time from when a patient has been screened to when the patient can be included in the trial is 14-28 days, which means that we will see an increase in the number of patients included in March. So far, 9 patients have been included in the trial and approximately 100 patients are planned to be screened in order for 80 patients to be included. The Company estimates that the rate of recruitment is in line with the target; fully recruited trial in November 2018.

In the open, investigator initiated trial DIAGNODE-1, all 12 patients have been followed for 6 months. 9 patients have been followed up to 15 months, of which 4 patients have been followed throughout the trial, 30 months. All 12 patients will have completed their 15-month visit at the end of the summer. In addition to 15-month results for all patients, Diamyd Medical will monitor the trial at earlier times prior to meetings with potential partners.

### **GAD production**

The current batch of formulated Diamyd® -vaccine (recombinant GAD formulated in alum) lasts until 2021. Further manufacturing of recombinant GAD, the active component of the Diamyd®-vaccine has, as previously announced, been ordered from Protein Sciences Corporation and a review of the manufacturing process, a GAP analysis, has been conducted to identify any steps in the process that can be improved before the new batches are produced.

### **Possible new LADA trial**

Diamyd Medical has indentified investigator interest to evaluate Diamyd® in patients diagnosed with LADA (Latent Autoimmune Diabetes in Adults). LADA is an autoimmune form of diabetes, similar to type 1 diabetes but diagnosed later in life and with a slower disease progression. A possible LADA-trial would be based on intralymphatic administration of Diamyd® analogous to the DIAGNODE-1- and DIAGNODE-2 trials and would not be financed by present funds, but with grants, if such financing should be granted.

### **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.

**For further information, please contact:**

Ulf Hannelius, President and CEO  
Phone: +46 736 35 42 41  
E-mail: [ulf.hannelius@diamyd.com](mailto: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](mailto:info@diamyd.com) Reg. no.: 556242-3797 Website: [www.diamyd.com](http://www.diamyd.com)

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