



Press release, September 16, 2019

## **Patients will be offered longer participation in the European Phase IIb trial with the diabetes vaccine Diamyd®**

Following approval from the Competent Authorities and Ethics Committees in Spain, the Czech Republic, Sweden and the Netherlands, Diamyd Medical can now offer the patients participating in the diabetes trial DIAGNODE-2 who have not yet performed their last visit at 15 months, to be included in a 9 month extension of the trial, which means that these patients will be followed for a total of 24 months. Top-line results of the trial will, as previously announced, be presented after 15 months, in the third quarter of 2020. The purpose of the longer follow-up is to further strengthen the regulatory package with safety and efficacy data prior to a potential earlier market application.

### **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. Those patients who have not yet performed their last 15-month visit will be offered to participate in an extension for another 9 months. 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](http://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](mailto:info@fnca.se).

### **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: <https://www.diamyd.com>

The information was submitted for publication, through the agency of the contact person set out above, at 15.35 CET on September 16, 2019.