



Press release, April 14, 2020

## **The European Patent Office grants patent for intralymphatic administration of the diabetes vaccine Diamyd®**

*The granted patent is valid until 2035 and provides central protection for the diabetes vaccine Diamyd®. In particular, the patent protects the intralymphatic administration method that is now being evaluated in the Phase IIb trial DIAGNODE-2 and which previously showed positive results in the Phase I/II trial DIAGNODE-1.*

“These news are very gratifying”, says Ulf Hannelius, CEO of Diamyd Medical. “The patent gives us extended protection for the diabetes vaccine Diamyd® in Europe, one of the most important pharmaceutical markets in the world”.

Diamyd Medical already holds, as part of an exclusive license from the University of California, Los Angeles (UCLA), patent protection in the United States, which is valid until 2032 for the treatment of diabetes with GAD, the active component of the diabetes vaccine Diamyd®. The new approval strengthens and extends the protection of GAD for the treatment of autoimmune diabetes in Europe. Diamyd Medical has also, through other patent applications, applied for patents for the treatment of patient subgroups defined by HLA genotypes and for various biomarkers.

In addition, the diabetes vaccine Diamyd®, independently of patent protection, enjoys as a biological drug twelve and ten years market exclusivity from the date of market approval in the US and Europe respectively. The FDA (US) has also granted Diamyd® so-called orphan drug status, which provides seven years of market exclusivity from the date of market approval.

### **About intralymphatic administration**

The purpose of administering directly into the lymph node is to, in a safe and simple manner, increase the effect of antigen-specific immunotherapy, a therapy based on the use of endogenous substances to reprogram the body's immune system in autoimmune diseases. Antigen-specific intralymphatic immunotherapy (AS-ILIT) differs from the traditional method where antigen is injected under the skin and then transported by immune cells to the lymph nodes. Instead, the injection is made directly into the lymph node, where the immune cells are trained. From there, the cells spread through the body, including to the pancreas where the reprogrammed cells are intended to create a changed response to the autoimmune attack on the insulin-producing beta cells. Intralymphatic administration has previously been evaluated in the allergy field where it has been shown to result in a stronger clinical and immunological effect. Here, several trials have shown that very small amounts of allergen administered directly into the lymph node provide the same effect and safety as significantly higher amounts of allergen injected under the skin for a prolonged period of treatment. DIAGNODE-1, that reported positive top-line results in December 2019, is the first clinical trial to evaluate the administration route in an autoimmune disease with the aim to induce immunological tolerance against an endogenous antigen. DIAGNODE-1 has paved the way for the double-blind and placebo-controlled trial DIAGNODE-2 with the aim of verifying the results from DIAGNODE-1. DIAGNODE-2 was reported fully recruited in May 2019 and results are expected to be presented in Q3 2020.

### **About Diamyd Medical**

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is 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 significant effect in some pre-specified subgroups. Results from the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes, are expected to be presented in the third quarter of 2020. 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).

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