Press release, April 24, 2020

Japan grants patent for intralymphatic administration of the diabetes vaccine Diamyd®

The patent now granted by the Japan Patent Office is valid until 2035. Diamyd Medical recently announced the grant of the corresponding patent in Europe. The patents primarily protect the administration method of Diamyd® 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.

"Having this patent granted in Japan is an important addition to our IP portfolio", says Ulf Hannelius, CEO of Diamyd Medical. "Japan is one of the largest pharmaceutical markets in the world and the patent will increase our ability to enter into commercial partnerships for Diamyd®".

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®. In addition to the patent granted in Japan, Diamyd Medical holds patent protection in Europe for intralymphatic administration of Diamyd® valid untl 2035. 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 evlauated 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. A new facility for vaccine manufacturing is being set up in Umeå with the first priority to receive the process technology for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine 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.

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