Press Release, May 7, 2018

Results supporting intralymphatic administration of Diamyd® published in the Journal of Diabetes Research

New results with the diabetes vaccine Diamyd®, comparing the immune responses after intralymphatic administration with immune responses after administering the vaccine subcutaneously, were published today in the Journal of Diabetes Research. The article, authored by researchers at Linköping University, describes that a more favorable immune response is achieved after intralymphatic treatment which may correlate with clinical effect. The results have generated patents filed by Diamyd Medical.

"These results are important as they support our strategy with intranodal treatment, and give a more detailed picture of why Diamyd® delivered directly into the lymph node seems to increase the efficacy of the vaccine," says Ulf Hannelius, CEO of Diamyd Medical.

The published results have generated patents filed by Diamyd Medical which enable the possible development and commercialization of biomarkers that can be used to tailor treatment with the diabetes vaccine Diamyd®.

The article compares the immune response of six patients from the ongoing clinical trial DIAGNODE-1 with six age and gender matched patients from the completed DIABGAD-1 trial. The examined patients from DIABGAD-1 received two high doses (20 µg / dose) of Diamyd® administered one month apart subcutaneously (under the skin), while those in DIAGNODE-1 received three low doses (4 µg / dose) of Diamyd® administered one month apart directly into the lymph node. In both trials the treatment was combined with oral vitamin D.

The results show that three low doses administered directly into the lymph node gives rise to an antigen-specific immune response characterized by lower immune cell proliferation, a non-inflammatory cytokine secretion pattern dominated by IL13 and a relative decrease of IgG1 antibodies in favor of the antibody subclasses IgG2, IgG3 and IgG4. These results are particularly evident in the two patients who demonstrate the best clinical response. Intralymphatic administration also generates many times higher levels of antibodies compared to two higher doses administered under the skin. Unlike intralymphatic treatment, the immune response generated by subcutaneous treatment is characterized by a proliferation of immune cells, a cytokine secretion pattern dominated by the cytokine IFN gamma and predominantly IgG1 antibodies after 180 days.

The article is available on https://www.hindawi.com/journals/jdr/aip/9391845/

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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