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New trial with Diamyd® in autoimmune diabetes has started recruiting patients in Norway

GADinLADA is the first clinical phase II trial with the diabetes vaccine Diamyd® administered directly into the lymph node in patients with the form of autoimmune diabetes called LADA (Latent Autoimmune Diabetes in Adults).

The investigator initiated clinical phase II trial, GADinLADA, is now open for recruitment at the Norwegian University of Science and Technology in Trondheim (NTNU), in cooperation with St. Olav's University Hospital, Trondheim. The trial will also be conducted in Sweden at the Center for Diabetes, the Academic Specialist Center, an academic specialist unit that is run in collaboration between the Health Care Services Stockholm County, Karolinska Institute and Karolinska University Hospital, and the recruitment is expected to start during the spring. In total, the trial encompasses 15 patients between the ages of 30 to 70 years diagnosed with LADA within the last 12 months who are not yet on insulin therapy.

“GADinLADA is an important trial addressing a significant unmet medical need in diabetes, says Ingrid K Hals, PhD and Sponsor's representative for the trial. “We see great potential with the diabetes vaccine Diamyd® to preserve endogenous insulin production and potentially delay or prevent the initiation of insulin therapy in patients diagnosed with LADA.”

The purpose of the trial is to evaluate the safety of intralymphatic treatment with Diamyd® in LADA patients and to continuously evaluate the immunological and clinical response over a one-year period. Sponsor of the trial is the Norwegian University of Science and Technology with Ingrid K Hals as sponsor representative. Diamyd Medical contributes with study drug and expertise. For more information about the GADinLADA trial, please visit www.GADinLADA.com.

“Disease-modifying drugs like the diabetes vaccine Diamyd® are integral to addressing the ever increasing prevalence of diabetes in the world,” says Ulf Hannelius, CEO of Diamyd Medical. “Our diabetes vaccine is uniquely suited to target the autoimmune form of diabetes; type 1 diabetes and LADA. The GADinLADA trial is an important step forward in developing a new treatment paradigm for diabetes.”

About LADA

Latent Autoimmune Diabetes in Adults (LADA) represents close to 10% of patients diagnosed with type 2 diabetes. LADA is characterized by an ongoing autoimmune destruction of the insulin-producing beta cells, a process similar to that of type 1 diabetes, but slower. Although research categorizes LADA as autoimmune diabetes, the disease is still in most cases treated according to the guidelines for type 2 diabetes. LADA patients are usually not insulin dependent at diagnosis, but for most patients, insulin therapy is required within a few years of diagnosis.

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.

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