

GeNeuro Initiates Phase 2a Study with GNBAC1 in Type 1 Diabetes in Australia

- Type 1 Diabetes is the second GNBAC1's indication after Multiple Sclerosis
- Placebo controlled randomized Phase 2a study evaluates drug candidate targeting potential causal factor in 60 recently diagnosed adults
- Results expected by 3Q2018

Geneva, Switzerland, 18 April 2017 - 7:30am CEST - GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for neurological disorders and autoimmune diseases, announced today the initiation of a Phase 2a clinical study in Australia with GNBAC1 in patients with Type 1 diabetes (T1D). GNBAC1 is a monoclonal antibody designed to neutralise MSRV-Env, a pathogenic protein that has been detected in the pancreas of T1D patients. GeNeuro is already evaluating GNBAC1 in Phase 2 clinical studies in patients with multiple sclerosis (MS), a disease in which evidence shows MSRV-Env to be a potential causal factor.

“Our extensive research on human endogenous retroviruses (HERVs) has suggested that there could be a causal role for MSRV-Env in other autoimmune diseases in addition to our lead program in multiple sclerosis. In Type 1 diabetes, MSRV-Env has been found in the pancreas of over 50 percent of patients post-mortem,” said Hervé Perron, Chief Scientific Officer of GeNeuro. “Our preclinical studies have showed that MSRV-Env causes a dose-dependent inhibition of insulin production, both in vitro and in animal models. These data, presented in February at the 2017 JDRF nPOD Annual Scientific Meeting in Florida, USA, and to be published later this year, provide a compelling rationale to start clinical studies in these diabetic patients.”

The placebo-controlled, randomized Phase 2a study will evaluate GNBAC1 in 60 recently diagnosed adults at over 10 centers in Australia. The primary endpoint will be safety in this new patient population, with secondary endpoints measuring the link between response and MSRV-Env biomarkers, measurement of insulin production based on C-peptide levels and other T1D-related biomarkers, such as insulin consumption, glycaemia and production of anti-beta cells antibodies. Last patient enrolment is expected by end 2017 and data from this study are expected during the third quarter 2018.

Australia has one of the highest incidences of Type 1 diabetes per capita in the world. With an extensive network of researchers and clinical sites as well as funding support from the Government, Australia offers a world-class environment to conduct clinical studies in Type 1 diabetes.

“The start of this T1D clinical study is a significant step for GeNeuro, as we open a new avenue of treatment for T1D patients addressing a potential cause of this disease, just as we are doing in our MS clinical studies,” said Jesús Martín-García, Chairman and CEO of GeNeuro. “We look forward to reporting data from our ongoing MS clinical studies, starting with CHANGE-MS early in the fourth quarter this year.”

About Type 1 Diabetes

Type 1 diabetes, usually first diagnosed in children, is caused by an immune response directed against the insulin producing cells of the pancreas. There is no cure for this ‘autoimmune’ disease, which means patients need life-long with insulin replacement therapy. This treatment is often associated with several debilitating complications, including heart disease, blindness, and kidney disease, among others.

About GNBAC1

The development of GNBAC1 is the result of 25 years of research into human endogenous retroviruses (HERVs), including 15 years at Institut Mérieux and INSERM, a French national medical research institute. Found in the human genome, certain HERVs have been linked to various autoimmune diseases. Researchers have demonstrated that the toxic Env protein, associated with MSRV (Multiple Sclerosis RetroVirus) and identified in patients with MS, particularly in active lesions, and in the pancreas of T1D patients. By neutralising MSRV-Env, GNBAC1 could at the same time block these pathological inflammatory processes and restore remyelination in MS patients and maintain insulin production in T1D patients. As MSRV-Env has no known physiological function, GNBAC1 is expected to have a good safety profile, without affecting the patient's immune system, as observed in all clinical trials to date.

About GeNeuro

GeNeuro's mission is to develop safe and effective treatments against neurological disorders and autoimmune diseases, such as multiple sclerosis, by neutralizing causal factors encoded by HERVs, which represent 8% of human DNA.

GeNeuro is based in Geneva, Switzerland and has R&D facilities in France at sites in Archamps, Haute-Savoie and in Lyon. It has 30 employees and rights to 16 patent families protecting its technology.

For more information, visit: www.geneuro.com

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