GeNeuro Announces First Patient Treated in Phase 2a Study with GNbAC1 in Type 1 Diabetes

- Australian Phase 2a clinical study plans to enroll 60 adult patients in over 10 centers
- Last patient enrolment is expected by end 2017

Geneva, Switzerland, 19 June 2017 – 07:30 am CEST – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for autoimmune diseases, announced today that the first patient has been treated in its Australian Phase 2a study of GNbAC1 in type 1 diabetes. This is GNbAC1’s second indication after multiple sclerosis, for which an international Phase 2b study is ongoing in 260 patients.

GNbAC1 is a monoclonal antibody designed to neutralize a pathogenic, viral envelope protein, encoded by a human endogenous retrovirus (HERV). HERVs are the result of ancestral, retroviral DNA insertions, currently estimated to account for up to 8% of the human genome. The humanized IgG4 monoclonal antibody GNbAC1 targets the envelope protein (Env) encoded by a member of the HERV-W family, the multiple sclerosis-associated endogenous retrovirus (MSRV). This protein has been detected in patients with multiple sclerosis and in the pancreas of patients with type 1 diabetes. It is thought to be a causal factor of these diseases.

“We have been accumulating knowledge that this pathogenic protein may be a key factor in the development of autoimmune diseases other than multiple sclerosis. The objective of this Phase 2a study is to demonstrate GNbAC1’s safety and potential benefit in preserving pancreatic function in patients with type 1 diabetes,” said François Curtin Chief Operating Officer of GeNeuro. “By targeting a potential cause of type 1 diabetes, GNbAC1 may lead to a paradigm shift for millions of patients throughout the world.”

“The need for new treatments for type 1 diabetes is very high. Preclinical data show that GNbAC1 provides an innovating and promising approach to address this important medical need. This is why I am pleased with the launch of this clinical study,” added Associate Prof. Richard W. Simpson, Eastern Clinical Research Unit of Monash University (Victoria, Australia), national investigator for the study.

This randomized, placebo-controlled Phase 2a study will evaluate GNbAC1 in 60 recently diagnosed adult patients in over 10 centers in Australia. The incidence of type 1 diabetes in Australia is among the highest in the world. The primary endpoint is the safety of GNbAC1 in this new population of patients. Secondary endpoints will measure the link between treatment response and MSRV-Env biomarkers of pancreatic function, insulin production based on peptide C levels, and other biomarkers associated with type 1 diabetes, such as insulin consumption, glycemia and production of diabetic auto-antibodies. Last patient enrolment is expected by the end of 2017 and preliminary results are expected during the third quarter 2018.

Jesús Martin-Garcia, Chairman and CEO of GeNeuro concluded: “We welcome the treatment of our first patient in the Phase 2a study with GNbAC1 in type 1 diabetes, on track with our previously announced schedule. The launch of this Phase 2a study is a new significant milestone for GeNeuro and for the use of GNbAC1 not only in multiple sclerosis, but also in other autoimmune diseases known to be associated with the presence of MSRV-Env protein.”
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. In the United States alone, approx. 1.8 million cases have been diagnosed\(^1\). There is no cure for this autoimmune disease, which means patients need life-long treatment with insulin replacement. This treatment is often associated with several debilitating complications, including heart disease, blindness, and kidney disease, among others. The TD1 market represented $6.6bn worldwide sales in 2013\(^1\).

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 neutralizing 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 31 employees and rights to 16 patent families protecting its technology.

For more information, visit: www.geneuro.com

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\(^1\) Source: GlobalData, Cowen & Company, The Environmental Determinants of Diabetes in the Young