Press release

GeNeuro Announces Positive 6-Month Phase IIa Data for GNbAC1 in Adults with Type 1 Diabetes

- Phase IIa RAINBOW study met all primary safety endpoints in this new patient population
- Opens path for development in larger populations with more recent disease onset

Geneva, Switzerland, 26 September 2018 – 7:30am CEST – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurological and autoimmune diseases, announced that its Phase IIa study of GNbAC1 in type 1 diabetes (T1D) met the primary endpoint of safety in this new patient population. GNbAC1 is a monoclonal antibody designed to neutralize a pathogenic envelope protein, pHERV-W Env, which has been detected post mortem in about two thirds of the pancreas of patients with T1D.

There were no serious related adverse events in the treatment arm, and the number of adverse events was lower with GNbAC1 than with placebo. No pharmacodynamic parameter showed any detrimental effect of GNbAC1 administration, irrespective of disease duration, concomitant treatment or insulin administration mode. No immunogenicity was observed, and no anti-drug antibodies were measured over the period. This confirms the very good tolerance of GNbAC1, in combination to standard treatment in this new patient population. The absence of any safety signal seen thus far opens the door to trials in larger diabetic populations, potentially in pediatric patients who represent 80% of cases at onset, and where disease modifying therapies are sorely needed.

All pharmacodynamic markers remained stable over time, without separation between the groups in this small population of adult patients with a well-controlled disease, characterized by high residual C-peptide and moderate HbAc1 levels, and low insulin consumption. Some encouraging signals were observed, such as a 32% reduction in the total number of hypoglycemic episodes in the treated group versus placebo ($p<0.0001$). Also noted was a 21% decrease of anti-insulin antibodies in the treatment group, versus an increase of 23% in the placebo group ($p<0.01$). But given the low occurrence of events in this well-controlled population and the small size of the Phase IIa cohort, these signals require confirmation through investigation in larger populations with a more recent onset.

"Meeting the primary objective of safety in this Phase IIa study with GNbAC1 in patients with type 1 diabetes supports our approach in targeting pHERV-W Env in combination with concomitant medications in a new therapeutic setting" said Dr. François Curtin, Chief Operating Officer of GeNeuro. *"We are breaking new biological ground with this study of a drug targeting pHERV-W Env in type 1 diabetes. These results provide the basis for testing this potential disease modifying approach in larger populations, potentially in pediatric patients."*

GNbAC1 is a monoclonal antibody designed to neutralize a pathogenic envelope protein, pHERV-W Env, encoded by a member of the Human Endogenous Retrovirus W family. This protein has been detected post mortem in about two thirds of the pancreas of patients with T1D, its toxicity on the pancreas has been validated in preclinical models, and it is thought be a key factor in the onset and development of the disease. Neutralizing the toxicity induced by pHERV-W Env in the pancreas may provide a specific and safe disease modifying therapy for T1D patients.

The Phase IIa randomized, placebo-controlled, signal finding study (RAINBOW) evaluated GNbAC1 in 64 adult patients diagnosed with T1D for up to 4 years, in 12 centers in Australia. The primary endpoint of the study was safety of GNbAC1 administration in combination with T1D treatments. Secondary endpoints measure T1D biomarkers such as HbA1c, insulin production based on peptide C levels, and other biomarkers associated with type 1 diabetes, such as insulin consumption, glycaemia and production of diabetic auto-antibodies. Detailed 6-month results will be presented at the Clinical Trials in Diabetes Congress on December 3-4, 2018 in Vienna, Austria. 12-month results will be available in 1Q2019, and GeNeuro will now start planning further clinical trials in T1D.

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 treatment with insulin replacement. This treatment is often associated with several debilitating complications, including heart disease, blindness, and kidney disease, among others.

About GeNeuro

GeNeuro's mission is to develop safe and effective treatments against neurological disorders and autoimmune diseases, such as multiple sclerosis and Type 1 Diabetes, 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 Lyon, France. It has 28 employees and rights to 17 patent families protecting its technology.

For more information, visit: www.geneuro.com

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