GeNeuro Presents Phase 2b Data Demonstrating Neuroprotective Effect of GNbAC1 in Multiple Sclerosis Patients at ECTRIMS 2018

- Positive effects observed on key neuroprotection endpoints related to MS disease progression
- Neuroprotective effects also seen in non-active MS patients
- Confirmation of safety and tolerability

Geneva, Switzerland, and Berlin, Germany, 15 October, 2018 – 7:30 CEST – GeNeuro (Euronext Paris: CH0308403085 – GNRO) announced today that data from its CHANGE-MS Phase 2b study of GNbAC1, a novel and promising therapeutic approach for the treatment of multiple sclerosis (MS), demonstrating a consistent effect on key neuroprotection endpoints was presented at the 34th Congress of the European Committee for Treatment and Research on Multiple Sclerosis (ECTRIMS 2018). The data showed that GNbAC1 administration for 12 months had a significant positive impact on key neuroprotection markers known to be linked to disease progression. Importantly, further analysis showed that these neuroprotective effects were at least as prominent in the inactive subpopulation, the precise group of patients who are not served well with currently-available disease modifying treatments. GNbAC1 is a monoclonal antibody designed to neutralize a pathogenic protein encoded by a member of the human endogenous retroviruses (HERV-W) family, pHERV-W Env.

"The final analyses of the CHANGE-MS, Phase 2b study showed consistent neuroprotective benefits with GNbAC1. Importantly, these benefits were prominent in the inactive sub-population of patients in this study, precisely the group of MS patients that are sub-optimally treated with currently available therapies. These results appear to be the outcome of a completely new mechanism of action targeting a cause of MS progression", said **Prof. Hans-Peter Hartung, Chairman of the Department of Neurology of the University Hospital Düsseldorf and principal investigator of the CHANGE-MS study**.

"*These positive Phase 2b results demonstrating the neuroprotective effect of GNbAC1 suggest that it could be used as a single agent on progressive MS populations without active inflammation as well as synergistically with existing anti-inflammation MS drugs*", **stated Jesús Martin-Garcia, CEO of GeNeuro.** "*This provides an additional element to our future development plans as well as discussions with potential licensing partners.*"

CHANGE-MS Data
In this 270-patient study, MRI showed a coherent neuroprotective positive effect on brain atrophy. cortical and thalamic atrophy showed relative volume reductions of 31% and 72%, respectively, between the highest dose and control group*[1], with a statistically significant dose-relationship for both (p=0.045 and P=0.014, respectively). Whole brain atrophy showed a 29% relative reduction in brain volume change over 12 months for the highest dose versus the control group, with a trend in dose-relationship (p=0.079).

In addition, number of T1 hypointense lesions or black holes, a marker of permanent tissue destruction in the brain of at least 14mm^3 volume, was reduced by 63% (p=0.014) at the end of the study in the 18mg/kg versus control group.

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[1] *control group: defined as patients originally randomized to placebo for the first 6 months, and then re-randomized to one of the active therapy arms for the second period of 6 months.*

The Magnetization Transfer Ratio (MTR) signal of 18mg/kg GNbAC1 was remarkably conserved across all of the periventricular and cerebral cortical bands examined, indicating preservation of myelin integrity with GNbAC1 treatment.

For most MRI measures of neuroinflammation, all groups improved over the 12 month period, however there was no significant separation between treatment groups.

GNbAC1 continued to show an excellent tolerability profile throughout the study.

About CHANGE-MS Phase 2b study
(**C**linical trial assessing the **H**ERV-W Env **An**tagonist **G**NbAC1 for **E**fficacy in **M**ultiple **S**clerosis)

- Randomized, double-blind, placebo-controlled study of 270 RRMS patients in 50 clinical centers in 12 European countries
- 6 month study with extension up to one year for secondary endpoints
- Primary endpoint: assess the efficacy based on the number of inflammatory lesions seen on repeated brain MRI, assessed at the end of the placebo-controlled period
- Secondary endpoints: MRI measures of neurodegeneration, clinical parameters at 6 and 12 months

About Multiple Sclerosis (MS)

MS is a disease of the central nervous system (brain and spinal cord) that affects more than two million people worldwide, with most patients being diagnosed between the ages of 20 and 40 years.

MS is a consequence of inflammatory and neurodegenerative processes leading to damage of the protective myelin sheath surrounding the neurons, and of the neurons themselves, what is called neurodegeneration. This process hampers nerve impulses from travelling between the brain and the rest of the body, thereby causing the symptoms associated with this disease. Preclinical research demonstrated that pathogenic HERV-W protein negatively impacts myelin restoration by directly inhibiting oligodendrocyte precursor cells (OPC), and induces inflammation by microglia activation. Relapsing-remitting multiple sclerosis (RRMS) is characterised by infrequent, acute exacerbations with full or partial recovery between attacks. All currently available Disease Modifying Treatments act on the inflammatory aspect of the disease. However, neurodegenerative processes play a major role in developing of long term disability in all forms of MS, both relapsing and progressive.

About GNbAC1

GNbAC1 is a monoclonal antibody designed to neutralize a pathogenic protein encoded by a member of the human endogenous retroviruses (HERV-W) family, pHERV-W env. In a phase 2b clinical study of 270 RRMS patients, GNbAC1 was found to be safe and demonstrated a consistent benefit on MRI measures of neurodegeneration associated with disease progression, including a reduction in T1 black hole formation and brain atrophy. GNbAC1 is also being investigated in a Phase 2a study of adults with Type 1 diabetes.

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 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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