Press release

GeNeuro Phase 2b Multiple Sclerosis Study Recruitment Reaches Halfway Mark Ahead of Schedule

- Therapeutic candidate GNbAC1 is first to target potential primary cause of MS
- Over 130 of 260 patients enrolled
- Clinical trial design presented during ECTRIMS Congress
- Primary data read-out confirmed in 4Q2017

Geneva, Switzerland, 14 September 2016 – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for autoimmune diseases including multiple sclerosis (MS), today announced that enrollment has reached the halfway mark, ahead of schedule, in the CHANGE-MS Phase 2b study of GNbAC1 in patients with relapsing-remitting multiple sclerosis (RRMS). GeNeuro provided the update at the 32nd ECTRIMS Congress, the world's largest international conference devoted to basic and clinical research on MS, being held in London, UK (14-17 September).

"Recruitment is progressing very well and faster than expected. It demonstrates the strong interest in this pioneering new treatment for MS. We remain on schedule to report initial results during Q4 2017," stated Jesús Martin-Garcia, Chief Executive Officer at GeNeuro. "MSRV-ENV is expressed in the active lesions of all types of MS. With this study, we believe we will establish the role of MSRV-ENV as a causal factor of MS and hopefully provide patients with a new and powerful avenue of therapy."

GNbAC1, the first clinical stage therapeutic candidate that directly targets a potential cause of MS, is a monoclonal antibody designed to neutralize MSRV-Env, a protein that has been shown to have both a pro-inflammatory action as well as the ability to stop the differentiation of the cells responsible for remyelinating brain lesions. By neutralizing MSRV-ENV, GNbAC1 could block a key factor promoting the inflammation on the plaques, as well as allowing the remyelination repair process to restart. Existing therapies for MS target the immune system of the patient to dampen the severity of the immune-mediated attack, while GNbAC1 seeks to neutralize a potential primary cause of this autoimmune disorder.

The double-blind, placebo-controlled study, CHANGE-MS (**C**linical trial assessing the **H**ERV-W Env **An**tagonist **G**NbAC1 for **E**fficacy in **M**ultiple **S**clerosis) is slated to enroll 260 patients in 69 clinical centers in 13 European countries. The primary endpoint measures efficacy based on the number of new T1 enhancing lesions on monthly brain MRI, assessed from weeks 12 to 24 of the placebo-controlled period. Secondary endpoints include: increase in T2 lesion volume through week 24, change in magnetization transfer ration (MTR), change in brain volumes, annualized relapse rate, percentage of patients with EDSS[1] progression confirmed at 3 months and change in MS functional composite scores from baseline to week 48, including sub-scale scores.

"We are looking forward to the results of this study as CHANGE-MS is based on gold standard trial design for MS products in Phase 2 development. This provides us with a solid base to ascertain the potential of improving the standard of care through this novel causal pathway," explained François Curtin, MD, Chief Operating Officer at GeNeuro.

[1] EDSS - Expanded Disability Status Scale

CHANGE-MS Phase 2b study is fully funded through GeNeuro's €362.5 million[2] partnership with Servier signed in 2014, in which Servier is involved in the development and potential commercialization of GNbAC1 in MS in territories outside the USA and Japan, with GeNeuro retaining full rights for these two territories. Subsequent to exercising the option agreement, Servier will also cover the costs of the MS Phase 3 global development program.

About Multiple Sclerosis

Multiple sclerosis (MS) is a disabling neurodegenerative autoimmune disease affecting approximately 2.5 million people worldwide, according to the Multiple Sclerosis Foundation. Driven by inflammatory and neurodegenerative processes, MS damages the myelin sheath, the material that surrounds and protects nerve cells, resulting in axonal damage in the brain and spinal cord. This slows down or blocks nervous conduction between the brain and the body, which leads to the symptoms of MS.

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. Specifically, MSRV-ENV, which is found on the active lesions of MS patients, has been shown to have both a pro-inflammatory action via interaction with the TLR4 receptor of innate immunity, as well as to stop the differentiation of oligodendrocyte precursor cells, which are responsible for remyelinating brain lesions. By neutralizing MSRV-ENV, GNbAC1 could block a key factor promoting the inflammation on the plaques, as well as allowing the remyelination repair process to restart. 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; a new frontier pioneered by GeNeuro since 2006 and based on research by Institut Mérieux and INSERM.

GeNeuro is based in Geneva, Switzerland and has R&D facilities in France at sites in Archamps, Haute-Savoie and Lyon. It has 23 employees and rights to 16 patent families protecting its technology.

For more information, visit: www.geneuro.com.

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[2] Maximum value, excluding royalties, dependent on achieving development milestones

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