

## GeNeuro Provides Update on GNbAC1 Multiple Sclerosis Clinical Program

- Enrollment completed for CHANGE-MS study ahead of schedule; 6-month top-line results now expected in early 4Q2017
- ANGEL-MS study launched, dosing of first patient expected in April 2017
- U.S. study in secondary progressive MS patients planned for 2H 2017

**Geneva, Switzerland, 3 January 2017** – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for autoimmune diseases, including multiple sclerosis (MS), today provided an update on GNbAC1, its multiple sclerosis drug candidate. GNbAC1, the first drug candidate directly targeting a potential cause of MS, is a monoclonal antibody designed to neutralise MSRV-Env, a pathogenic protein which has been associated with both the inflammatory and neurodegenerative components of the disease.

“Completing enrollment in CHANGE-MS several months sooner than previously anticipated is a significant achievement for our GNbAC1 development program and, most importantly, accelerates the timeline to potentially provide MS patients with a new and effective therapeutic option,” said Jesús Martin-Garcia, Chief Executive Officer at GeNeuro.

Full enrollment of the CHANGE-MS Phase 2b study of GNbAC1 has been completed, several months ahead of schedule, and is indicative of strong interest from physicians in this pioneering new treatment for MS. Based on this accelerated timeline, GeNeuro now expects the availability of top-line results from this study early in the fourth quarter of 2017, versus the previous estimate of by year-end 2017. The double-blind, placebo-controlled study, CHANGE-MS (**C**linical trial assessing the **HERV-W Env Antagonist GNbAC1 for Efficacy in Multiple Sclerosis**), is evaluating the efficacy of GNbAC1 in reducing the number of new inflammatory lesions as well as measures of neurodegeneration on brain MRI in patients with relapsing relapsing multiple sclerosis (RRMS). The CHANGE-MS Phase 2b study is fully funded through GeNeuro’s €362.5 million<sup>1</sup> [partnership with Servier, which was signed in 2014](#).

The recently announced ANGEL-MS (*Assessing the HERV-W Env **ANT**agonist **GNbAC1 for Evaluation in an open label Long-term Safety Study in patients with Multiple Sclerosis***) study has now been launched, offering all patients having completed the Phase IIb CHANGE-MS study the opportunity to continue their treatment for an additional two years, providing additional efficacy and tolerance data. The first patient completing 12 months in CHANGE-MS, eligible to continuing treatment through ANGEL-MS, is expected to enrol in April 2017. Like CHANGE-MS, the ANGEL-MS study will be fully funded by Servier.

GeNeuro continues to work on its submission package in preparation for clinical trials in the U.S. A Phase 2 study in secondary progressive MS patients, a patient population distinct from RRMS patients, is now anticipated to begin during the second half of 2017. This study will evaluate the effect of repeated doses of GNbAC1 on safety and biomarkers of microglial activation, remyelination and neuroprotection.

“2016 has been a transformative year for GeNeuro, with the success of our IPO, the full recruitment of CHANGE-MS and the further strengthening of our team in order to execute additional clinical trials in 2017. We look forward to initiating these new studies and to the availability of the interim 6-month results from CHANGE-MS at the beginning of the fourth quarter of 2017,” Mr. Martin-Garcia added.

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<sup>1</sup> Maximum value, excluding royalties, dependent on achieving development milestones

## 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. MS is the consequence of inflammatory processes directed against the myelin sheath, a protective sleeve surrounding the neurons. Myelin damage prevents the neurons from functioning properly and leads to their degeneration. It slows down or prevents nerve impulses from travelling between the brain and the rest of the body, thereby causing the symptoms associated to this disease.

## 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 MSR/V (Multiple Sclerosis RetroVirus) and identified in patients with MS, particularly in active lesions, stimulated the inflammatory processes via an interaction with the TLR4 receptor involved in the innate immune system, and blocked neuron remyelination. By neutralising MSR/V-Env, GNBAC1 could at the same time block these pathological inflammatory processes and restore remyelination. As MSR/V-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 Lyon. It has 30 employees and rights to 16 patent families protecting its technology.

For more information, visit: [www.geneuro.com](http://www.geneuro.com)

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