Servier and GeNeuro Announce Six-Month Results from CHANGE-MS Phase 2b Study in Multiple Sclerosis

- **GNbAC1 is well tolerated**
- **Anti-inflammatory effect not demonstrated at 6 months**
- **Analysis of full 12-month Phase 2b data expected 1Q18**

28 August 2017 – Servier and GeNeuro (Euronext Paris: CH0308403085 – GNRO) announced today 6-month results from the 12-month CHANGE-MS Phase 2b study of three doses of GNbAC1 for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS). The data showed that GNbAC1 is well tolerated and that there is no statistical difference at 6-months between GNbAC1 and placebo in the study's primary endpoint of reducing the number of cerebral Gad-enhancing lesions as measured by MRI, nor on the other MRI measures of neuro-inflammation. Relapses in the overall population decreased by over 50% relative to the year prior to study but there was no significant difference at 6 months between treated and placebo groups. Based on the unique mechanism of action and pharmacokinetics of GNbAC1, the study will continue, as planned, exploring potential benefits of the drug on MRI and clinical measures, including remyelination properties, with final results from the full 12-month expected in the first quarter of 2018.

CHANGE-MS Phase 2b study is a randomized, double-blind, placebo-controlled study of 270 RRMS patients in 50 clinical centers in 12 European countries. The primary endpoint at 6 months is an assessment of the efficacy of GNbAC1 based on the number of inflammatory lesions on brain MRI. Secondary endpoints at 12 months will also include MRI measures of neurodegeneration, clinical parameters, and biomarkers, including pathogenic pHERV-W env. The protein could be a causal factor in the development of multiple sclerosis.

"CHANGE-MS being a study evaluating an innovative approach not immunosuppressive in MS, a longer delay of action than seen with other drugs is possible. The 6-month data showed a good safety profile. From a clinical perspective, it is important to wait for the full 12-month results," **noted Prof Hans-Peter Hartung, chairman of the Department of Neurology of the University Hospital Düsseldorf and principal investigator of the CHANGE-MS study.**

"In line with Servier's commitment to bringing new safe and effective treatments to patients, we will continue working with GeNeuro to better understand the potential clinical benefits of this innovative drug, GNbAC1, and wait for the full results of the study at 12 months," **added Dr. Christian de Bodinat, Director of Servier's Neuropsychiatry Therapeutic Innovation Department.**

"GNbAC1 is a new way to treat MS patients, with a novel mode of action. Analysis of the data is ongoing to better understand potential therapeutic benefits," **stated Jesús Martin-Garcia, CEO of**

GeNeuro. *"We are fully committed to this technology and look forward to final results from this 12-month study, expected in the first quarter of 2018."*

GNbAC1 is a monoclonal antibody which neutralizes a retroviral pathogenic envelope protein (pHERV-W env) encoded by a member of the HERV-W family. Human endogenous retroviruses (HERVs) are ancestral retroviral DNA insertions in the human genome, thought to account for up to 8% of the human genome. The pHERV-W env protein is thought to be a causal factor in the development of multiple sclerosis and Type 1 diabetes. GeNeuro is currently conducting a Phase 2a study in Type 1 diabetes, with results expected during the third quarter of 2018.

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 centres in 12 European countries
- 12-month study with primary endpoint at 6 months and extension up to one year for secondary endpoints
- Primary endpoint at 6 months: at the end of the placebo-controlled period, to assess the efficacy based on the number of inflammatory lesions on brain MRI,
- Secondary endpoints: MRI measures of neurodegeneration, clinical parameters at 6 and 12 months, and biomarkers, including pHERV-W env

CHANGE-MS is fully funded through a partnership with Servier signed in 2014, in which Servier is involved in the development and potential commercialization of GNbAC1 in MS in territories ex USA and Japan. Under this agreement and depending on achievement of development milestones, GeNeuro could receive a maximum of €362.5M, excluding royalties.

About Multiple Sclerosis (MS)
MS is a disease of the central nervous system (brain, optic nerves and spinal cord) that affects more than two million people worldwide, with most people being diagnosed between the ages of 20 and 40 years. 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. Relapsing-remitting multiple sclerosis (RRMS), the most common clinical form of MS, is characterised by infrequent, acute exacerbations with full or partial recovery between attacks. It accounts for around 85% of all cases at onset.

About GNbAC1
The development of GNbAC1 is the result of more than 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 and neurodegenerative diseases. Researchers have demonstrated that the retroviral envelope protein encoded by a HERV-W family human endogenous retrovirus (pHERV-W), which has been identified in brain lesions of patients with MS, particularly in active lesions, stimulated inflammatory processes through an interaction with the TLR4 receptor of innate immunity and inhibited neuron remyelination. pHERV-W env has also been identified in the pancreas of Type 1 diabetes (T1D) patients. By neutralizing pHERV-W 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 pHERV-W env has no known physiological function, GNbAC1 is expected to have a good safety profile, without directly affecting the patient's immune system, as observed in all clinical trials to date.

About Servier
Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 148 countries and a turnover of 4 billion euros in 2016, Servier employs 21,000 people worldwide. Entirely independent, the Group reinvests 25% of its turnover

(excluding generic drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric disease, oncology and diabetes, as well as by its activities in high-quality generic drugs.

Servier has a solid commitment to neuropsychiatry and to proposing innovative therapies to patients suffering from neurological conditions. Its research teams are investigating new ways of treating diseases such as Alzheimer's and Parkinson's, as well as a broad range of neurodegenerative disorders, by targeting the toxic proteins that lead to neuron degeneration. The priority is to focus on the causes of the diseases rather than their symptoms. Currently, there are 5 projects at different stages of research in this promising area. Regarding development, where Servier's team has a strong expertise in international clinical development and in investigator training in neurology and psychiatry, current phase II/III projects focus on autism, major depressive disorder, post-stroke functional recovery and multiple sclerosis. This portfolio of innovative treatments is being developed with partners worldwide.

More information: www.servier.com

About GeNeuro

GeNeuro's mission is to develop safe and effective treatments against neurological disorders and autoimmune diseases, such as multiple sclerosis or 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 30 employees and rights to 16 patent families protecting its technology.

For more information, visit: www.geneuro.com

Contacts
For Servier
Karine Bousseau
Servier External Communications
Tel: +33 1 5572 4021 /+33 6.49.92.16.05
media@servier.com

For GeNeuro

GeNeuro	NewCap (France)	Halsin Partners	LifeSci Advisors
Jesús Martin-Garcia Chairman and CEO +41 22 794 50 85 investors@geneuro.com	Julien Perez (investors) +33 1 44 71 98 52 Nicolas Merigeau (media) +33 1 44 71 94 98 geneuro@newcap.eu	Mike Sinclair (media) +44 20 7318 2955 msinclair@halsin.com	Chris Maggos (investors) +1 646 597 6970 +41 79 367 6254 chris@lifesciadvisors.com

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