

GeNeuro Announces First Patients Treated in Phase 2b Study for Multiple Sclerosis

CHANGE-MS clinical study plans to enroll 260 patients in 13 European countries

Geneva, Switzerland, 31 May 2016 – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for autoimmune diseases including multiple sclerosis (MS), today announced that the first patients have been treated with its lead product, GNbAC1, in a Phase IIb study in relapsing-remitting multiple sclerosis (RRMS).

GNbAC1, the first drug candidate in clinical studies directly targeting a potential cause of MS, is a monoclonal antibody designed to neutralize MSRV-Env, a protein linked to the inflammatory and neurodegenerative components of the disease.

“The aim of this Phase 2b study is to demonstrate the efficacy of GNbAC1 as a treatment for MS patients. This new therapeutic approach, targeting MSRV-Env, seeks to neutralize an upstream source of inflammation and to restore the remyelination capacity of the brain,” explained François Curtin, MD, Chief Operating Officer at GeNeuro. “Blocking a causal factor in MS, as opposed to current treatments that interfere with the immune system, would open a new therapeutic option for MS patients.”

The double-blind, placebo-controlled study, CHANGE-MS (**C**linical trial assessing the **H**ERV-W Env **A**ntagonist **G**NbAC1 for **E**fficacy in **M**ultiple **S**clerosis) plans to enroll 260 patients in 69 clinical centers in 13 European countries. The primary endpoint will examine the cumulative number of active brain lesions determined by MRI after 6 months, followed by additional MRI and clinical measures at 12 months. Preliminary results are expected by fourth quarter 2017.

CHANGE-MS is fully funded through a €362.5 million¹ [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.

“Meeting this clinical milestone, the first since raising €33 million in our IPO in Paris in April 2016, is an important step in the development of GNbAC1 in MS with Servier. The successful IPO will now allow GeNeuro to extend MS studies of GNbAC1 into the US, where GeNeuro has kept all the rights, and initiate trials in other autoimmune diseases, including type-1 diabetes and CIDP (chronic inflammatory demyelinating polyneuropathy), an orphan neurological disease,” stated Jesús Martin-Garcia, CEO of GeNeuro.

About Multiple Sclerosis

Multiple sclerosis (MS) is an autoimmune disease affecting approximately 2.5 million people worldwide, according to the Multiple Sclerosis Foundation. Driven by inflammatory and neuro-degenerative 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.

¹ Maximum value, excluding royalties, dependent on achieving development milestones.

About GNbAC1

The development of GNbAC1 is the result of 25 years of research into human endogenous retroviruses (HERVs), including 15 years with the Mérieux Institute and INSERM, before GeNeuro was founded in 2006. 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 human endogenous retroviruses (HERV), which represent 8% of the human DNA; a new frontier pioneered by GeNeuro since 2006 based on 15 years of R&D at Institut Mérieux and INSERM.

GeNeuro is based in Geneva, Switzerland and has R&D facilities 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

About Servier

Servier is an independent French-based pharmaceutical company with a strong international presence in 148 countries. It employs more than 21,000 people. Its development is driven by the pursuit of innovation in the therapeutic areas of cancer, cardiovascular, metabolic, central nervous system, psychiatric, bone, muscle and joint diseases. In 2015, the company recorded a turnover of €3.9 billion. 28% of this turnover was reinvested in Research and Development.

For more information, visit: www.servier.com

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