GeNeuro and Servier announce ANGEL-MS extension clinical study in multiple sclerosis

• The ANGEL-MS extension study will offer the 260 patients enrolled in the on-going Phase IIb CHANGE-MS study the opportunity to continue their treatment for an additional two years and will provide additional efficacy and tolerance data.

Geneuro, Switzerland and Servier, France, 7 December 2016: GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for autoimmune diseases including multiple sclerosis, and Servier, a leading independent international pharmaceutical company, announce the setting-up of ANGEL-MS, a long-term extension study for patients with multiple sclerosis (MS) and treated with GNbAC1.

GNbAC1, developed by GeNeuro, is the first drug candidate directly targeting a potential cause of MS. GNbAC1 is a monoclonal antibody designed to neutralise MSRV-Env, a toxic protein potentially associated with the inflammatory and neurodegenerative components of the disease.

To collect long-term data on this new treatment, particularly on its tolerance, the durability of its effect and the patients’ quality of life, GeNeuro and Servier have decided to set up an the ANGEL-MS (Assessing the HERV-W Env ANtagonist GNbAC1 for Evaluation in an open label Long-term Safety Study in patient with Multiple Sclerosis) study, which is an extension of the CHANGE-MS study currently underway. ANGEL-MS will give patients an opportunity to continue their treatment. This study is expected to last two years and will start in April 2017, once the first patient included in the CHANGE-MS study will have completed the 12-month participation. GeNeuro is the study sponsor, and as with CHANGE-MS, the ANGEL-MS study will be fully funded by Servier.

As per the terms of its partnership signed with GeNeuro in 2014, Servier is funding the European, double-blind, and placebo-controlled clinical study on GNbAC1 CHANGE-MS (Clinical trial assessing the HERV-W Env Antagonist GNbAC1 for Efficacy in Multiple Sclerosis). The primary endpoint of this 12-month study is the cumulative number of active brain lesions shown on an MRI at 6 months. The primary results after 6 months are expected in Q4 2017.

ANGEL-MS will be conducted in parallel with any Phase III studies that might be launched based on the results of the CHANGE-MS study.
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 in some cases 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 MSRV (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 MSRV-Env, GNbAC1 could at the same time block these pathological inflammatory processes and restore remyelination. 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.

GeNeuro is based in Geneva, Switzerland and has R&D facilities in France at sites in Archamps, Haute-Savoie and Lyon. It has 28 employees and rights to 16 patent families protecting its technology.

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

About Servier

Servier is an international pharmaceutical company governed by a non-profit Foundation and headquartered in France. With a strong international presence in 148 countries and a turnover of 3.9 billion euros in 2015, Servier employs over 21,200 people worldwide. Corporate growth is driven by Servier’s constant search for innovation in five areas of excellence: cardiology, oncology, metabolism, neuropsychiatry and rheumatology, as well as by its activities in high quality generic drugs. Being completely independent, the Group reinvests 25% of Servier’s products turnover in Research and Development, and all its profits in its growth.

Servier has long-standing experience in neuropsychiatry and offers new treatments for patients with neurological and psychiatric disorders. Its research teams investigate primarily the causes of diseases rather than their symptoms. Servier has 11 on-going projects at various stages of development in this field, particularly for the treatment of Alzheimer’s disease, severe depression, post-stroke functional recovery and multiple sclerosis.

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