Press release

GeNeuro announces completion of recruitment of its long-COVID Phase 2 trial and confirms top-line results for June 2024

- **Over 200 patients randomized in this precision-medicine study, making it one of the largest randomized, double-blind, placebo-controlled trials against long-COVID in the world.**
- **Study evaluates the efficacy and the safety of the treatment with temelimab on the improvement in fatigue and cognitive impairment measures.**
- **The expression of the pathogenic W-ENV protein, which was a key inclusion criterion to enter this biomarker-based study, is confirmed in over 1/3 of patients screened.**
- **W-ENV is suspected to have a major role in the persistence of inflammation and in the neurological symptoms affecting these patients.**
- **Top-line results will be available in June 2024. Clinical success would open the path for accelerated pathways to make the drug available to this underserved population.**
- **While millions of patients are affected by long-COVID, GeNeuro's biomarker-based approach allows to identify those for whom the treatment may be relevant.**

Geneva, Switzerland, November 28, 2023 – 8:00 AM CET - GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company focused on stopping causal factors driving the progression of neurodegenerative and autoimmune diseases such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and Post-Acute Sequelae of COVID-19 (PASC, long-COVID or post-COVID), today announced the completion of the recruitment of its Phase 2 trial evaluating temelimab against long-COVID.

The trial "*Temelimab as a Disease Modifying Therapy in Patients With Neuropsychiatric Symptoms in Post-COVID 19 or PASC Syndrome*" is a randomized, placebo-controlled, biomarker-based, Phase 2 clinical trial assessing the effect of the treatment with temelimab on the clinical course of these symptoms. The trial has recruited 203 patients across 14 clinical centres in Switzerland, Spain and Italy. All enrolled patients receive 6 intravenous infusions of temelimab or placebo (1 to 1 randomization) over 24 weeks. The clinical endpoints will assess the efficacy and the safety of the treatment with temelimab on the improvement in fatigue and cognitive impairment measures.

The recruitment of the trial has already demonstrated that the expression of the pathogenic W-ENV protein, triggered by the SARS-CoV-2 infection, may continue long after the acute phase has been resolved. Over one third of the patients presenting long-COVID syndromes who were screened were positive to the presence of W-ENV in their blood. W-ENV is suspected to have a major role in the persistence of inflammation and in the neurological symptoms affecting these patients, and temelimab is a highly specific neutralizing anti-W-ENV-antibody. GeNeuro's precision medicine approach allows to identify, within the millions of patients affected by long-COVID, those for whom the treatment may be relevant.

"Long-COVID is proving to be a major unmet medical need as patients who are suffering from its impairing syndromes are often helpless. The patient response to the study as well as their dedication to participation has been very encouraging," **said Prof. Idris Guessous, Head of the Division of Primary Care Medicine at the Geneva University Hospitals and Principal Investigator of the study**. "*We hope that this trial targeting the pathogenic W-ENV protein will result rapidly into a personalized medicine approach, identifying and treating patients who may benefit from the therapy*."

"*W-ENV has been shown to be pro-inflammatory and pathogenic to nervous system cells. Its neutralization with temelimab, a highly specific antibody with an excellent tolerability profile, aims to improve symptoms of fatigue and cognitive impairment ("brain fog")*. *The trial will establish how much this neutralization impacts the clinical symptoms affecting long-COVID patients and, if substantial enough, temelimab could become a first disease-modifying therapy in this underserved new indication*, said **Prof. David Leppert, Chief Medical Officer of GeNeuro.** *"We are very grateful to the patients who have agreed to participate in this important study, and we also thank the teams of the 14 clinical centres for their great efforts in opening a new road."*

About Temelimab

The development of temelimab (GNbAC1) is the result of more than 25 years of research into human endogenous retroviruses (HERVs), including 15 years within Institut Mérieux and INSERM before GeNeuro was founded in 2006. HERVs have been incorporated into the human genome during the evolution of mankind and typically remain "silent genes", but may be activated under certain conditions and were found to be involved in the development of auto-immune diseases. The viral envelope protein encoded by the HERV-W family (W-ENV) has been found to be pro-inflammatory and pathogenic to nervous system cells. W-ENV is found in the brains of MS patients, and particularly in active lesions. In two Phase II multiple sclerosis trials Temelimab has shown promising results on MRI features and liquid biomarkers related to neurodegenerative processes such as brain atrophy.

Temelimab is a neutralizing anti-W-ENV-antibody; by this capacity it simultaneously blocks inflammatory and neurodegenerative processes. Given that W-ENV has no known physiological function, temelimab has demonstrated a good safety and tolerability profile in the current study, with no effect on the patient's immune system, which bears out the profile observed in all clinical trials carried out 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.

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

Contacts:

GeNeuro

Jesús Martin-Garcia
Chairman and CEO
+41 22 552 4800
investors@geneuro.com

NewCap (France)

Louis-Victor Delouvrier
+33 1 44 71 98 52
Arthur Rouillé (media)
+33 1 44 71 00 15
geneuro@newcap.eu

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