



Press release

GeNeuro Announces Last Patient Last Visit in its Post-COVID Trial and Confirms Top-Line Results by End of June 2024

- The GNC-501 study against Post-Covid completed the last patient visit
- The study's objective is to evaluate the efficacy and safety of temelimab on the improvement of fatigue and cognitive impairment measures associated with Post-Covid
- With 203 patients enrolled, GNC-501 is one of the largest randomized double-blind placebo-controlled precision-medicine trials in the post-COVID indication
- GeNeuro confirms the timelines for the finalization of the trial, with top-line data expected by the end of June 2024.

Geneva, Switzerland, May 16, 2024 – 8.00 am CEST – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing therapies for patients with 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 that the last patient enrolled in the GNC-501 trial of temelimab against post-COVID has now completed the study.

The trial "Temelimab as a Disease Modifying Therapy in Patients With Neuropsychiatric Symptoms in Post-COVID 19 or PASC Syndrome" (GNC-501) is a randomized, placebo-controlled, biomarker-based, Phase 2 clinical trial assessing the safety and the efficacy of the treatment with temelimab, a monoclonal antibody neutralizing the pathogenic HERV-W ENV protein. The trial has recruited 203 patients across 14 clinical centres in Switzerland, Spain and Italy.

All patients included in the study were tested positive for the expression of the HERV W-ENV protein, which is a key factor in the activation of the innate immune response and is suspected to have a major role in the persistence of inflammation and in the broad spectrum of neurological symptoms affecting patients with post-COVID. Over 1/3 of the patients screened had detectable W-ENV protein expression in blood, suggesting that temelimab could become a relevant treatment option for a large subset of this underserved patient population.

All enrolled patients received 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.

"With this last visit of the last patient, we have reached a key step towards the finalization of the GNC-501 study exploring a potential precision-medicine based treatment option for subjects suffering from post-COVID", said Dr. Anke Post, Chief Medical Officer of GeNeuro. "We thank all patients who have agreed to participate in this study, the largest of its kind up to date, and hope that the results at the end of June will confirm the potential of temelimab to relieve persistent symptoms such as fatigue and to impact the disease burden".

About temelimab

The development of temelimab 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 brain of patients with MS as well as COVID-19 and post-COVID. In two Phase II MS

trials, temelimab has shown target engagement and 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 all clinical trials carried out to date.

About GeNeuro

GeNeuro's mission is to leverage HERV biology to develop safe and effective treatments for the benefit of patients, by neutralizing causal factors encoded by HERVs that represent 8% of human DNA.

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

For more information, visit: www.geneuro.com







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