Independent Data Monitoring Committee recommends continuing the trial evaluating temelimab in Long COVID without any modifications

- As planned in the Protocol of the Study, the Independent Data Monitoring Committee (IDMC) met to review the unblinded safety and efficacy data of the first 90 patients after three months of treatment.

- Based on the planned interim analysis of efficacy and safety data, which included an analysis for futility, the IDMC recommended to “continue the trial without any modifications”.

- The study is evaluating the efficacy and safety of treatment by temelimab in terms of improving measures of fatigue and cognitive impairment. Results are expected in June 2024.

**Geneva, Switzerland, December 11th, 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 that, as planned in the Study Protocol, the Independent Data Monitoring Committee met to review the unblinded safety and efficacy data of the first 90 patients after three months of treatment.

Based on the planned interim analysis of efficacy and safety data, which included an analysis for futility, the IDMC recommended to “continue the trial without any modifications”.

The study “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 evaluating the effect of temelimab treatment on the clinical course of these symptoms.

This trial enrolled 203 patients in 14 clinical centers in Switzerland, Spain and Italy, who were affected by neurological syndromes post-COVID, and who tested 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.

Results are expected in June 2024.

**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.

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