GeNeuro is granted authorization by the Swiss Health Authority (Swissmedic) to initiate a Phase II study evaluating temelimab in patients with severe neuropsychiatric post-COVID syndromes

- **Use of GeNeuro's temelimab as part of the first personalized medicine approach in severe post-COVID neuropsychiatric syndromes**
- **Biomarker-based study to detect the presence of the pathogenic W-ENV protein and neutralize it with temelimab**
- **GeNeuro has previously received a grant of 6.4 million euros from the Swiss Federal Office of Public Health (SFOPH) to co-fund this clinical trial**

Geneva, Switzerland, May 11, 2022– 5.45pm CET – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurodegenerative and autoimmune diseases, such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and the severe neuropsychiatric consequences of COVID-19 (post-COVID), announces today it has received the authorization by the Swiss Health Authority (Swissmedic) to initiate a Phase II study evaluating temelimab in patients with severe neuropsychiatric post-COVID syndromes.

The GNC-501 study, entitled "Temelimab as a Disease Modifying Therapy in Patients with Neurological, Neuropsychological, and Psychiatric (=Neuropsychiatric) Symptoms in Post-COVID-19 or Post-Acute Sequelae of COVID-19 (PASC) Syndrome", will enroll 200 patients from Swiss and EU study centres suffering from severe neuropsychiatric syndromes post-COVID. The biomarker-based study will enrol only patients who are also tested positive for the pathogenic protein W-ENV, with the objective to reduce their invalidating conditions.

"*The presence of the pathogenic protein W-ENV in post-COVID patients provides a potential biological explanation for the very diverse neuropsychiatric symptoms many suffer from, but also a treatment opportunity by neutralizing W-ENV with temelimab, which is a very well tolerated antibody*" said Prof. David Leppert, Chief Medical Officer of GeNeuro. "*Our unique ability to test patients for the presence of W-ENV in their blood allows to select and treat only those patients who are likely to benefit from temelimab*".

Large-scale academic studies indicate that more than 10% of people infected with SARS-CoV-2 do not fully recover and/or develop new symptoms, with a high proportion of neurological and/or psychiatric disorders. With more than 500 million confirmed cases of COVID-19 worldwide, including more than 250 million in North America and Western Europe, this problem is now recognized as a major public health emergency, as it is affecting millions of people. GeNeuro is at the forefront in tackling this problem with the first personalized medicine approach with a biomarker-based treatment.

Studies published in 2021 have shown that W-ENV expression was triggered by SARS-CoV-2 in the white blood cells of about 20% of healthy donors, suggesting individual susceptibility. Moreover, recent studies have shown that the pathogenic W-ENV protein is detectable in the blood of 20-40% of post-COVID patients. This presence months after the initial COVID infection supports the biological hypothesis of its role in the long-term syndromes suffered by these patients.

GeNeuro has developed temelimab, a specific antibody against the W-ENV protein, which has shown promising results in Phase II trials in multiple sclerosis against MRI markers of neurodegeneration. Temelimab has shown excellent safety and tolerability in several hundred patients treated for 2 years or more. The ability to detect W-ENV in post-COVID patients with neuropsychiatric disorders allows to identify a well-defined group of patients that will be treated with the aim of improving their condition.

As previously mentioned, GeNeuro has received a €6.4 million grant from the Swiss Federal Office for Public Health (FOPH) to co-fund the Phase 2 clinical trial to treat post-COVID patients with severe neurological and psychiatric symptoms with temelimab, GeNeuro's anti-W-ENV antibody.

About GeNeuro

GeNeuro's mission is to develop safe and effective treatments for neurological disorders and autoimmune diseases, such as multiple sclerosis, by neutralizing the causative factors encoded by HERVs, which represent 8% of human DNA.

GeNeuro is headquartered in Geneva, Switzerland, and has R&D facilities in Lyon, France. It has rights to 17 patent families protecting its technology.

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

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