Press release

GeNeuro announces the completion of its ProTEct-MS study and confirms the March timeline for top-line results, provides a Business Update and Cash Position as of December 31, 2021

- Completion of ProTEct-MS Phase 2 Clinical trial of temelimab in multiple sclerosis (MS) with Karolinska Institutet / Academic Specialist Center of Stockholm
    - Top line results confirmed for March 2022

- Net Cash position of €5.5 million as of December 31, 2021 with financial visibility to Q1 2023, not including the first €3 million payment from Swiss Federal Office of Public Health (FOPH) grant for post-COVID project received in January 2022

Geneva, Switzerland, January 27, 2022 – 7:30am 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 severe neuropsychiatric consequences of COVID-19 (post-COVID), announced today that it has completed its ProTEct-MS clinical trial. The Company also reported its cash position as of December 31, 2021 and provided a business update.

"Despite the continuing challenges posed by the COVID-19 pandemic, 2021 has been a key year for GeNeuro and the development of our HERV platform," **said Jesús Martin-Garcia, CEO of GeNeuro**. *"Having completed the last-patient's last-visit yesterday for our ProTEct-MS trial at the Karolinska Institutet and the Academic Specialist Center (ASC) in Stockholm, Sweden, we confirm that results will be available by the end of March of this year. This will of course be a key milestone for the Company and for MS patients."*

The **ProTEct-MS** trial has been conducted at the Center for Neurology of ASC, the largest MS center in Sweden. The one-year Phase 2 trial has enrolled 40 patients whose disability progresses without relapses as they have previously received chronic anti-CD20-Ab therapy with rituximab. Results are expected to document the safety and tolerability of temelimab following higher doses (up to 54mg/kg/month), as well as efficacy based on the latest biomarkers associated with disease progression. Despite the availability of effective treatments against acute inflammation and relapses, about 80% of MS patients suffer from the progression of their disability over time, which remains the key unmet medical need in MS.

"*With the completion of patient visits in the ProTEct-MS trial, we now look forward to reporting out the efficacy and safety results by the end of March,*" commented **Prof. David Leppert, M.D., Chief Medical Officer of GeNeuro**. "*We would like to thank all the trial participants for their time and commitment to this important research effort, especially in the difficult circumstances of the past two years. We are also very grateful for the Karolinska/ASC team's dedication and commitment as we now work towards the disclosure of the results*."

OTHER PRODUCT DEVELOPMENT HIGHLIGHTS SINCE JANUARY 1, 2021

Post-COVID

During 2021, academic groups in Europe and North America produced unexpected but key scientific evidence showing that SARS-CoV-2 derepresses the expression of the pathogenic protein HERV-W ENV ("W-ENV") in susceptible individuals. W-ENV, which is temelimab's target in MS, has well documented pro-inflammatory and pathogenic properties to nervous system cells. Its detection in COVID-19 patients provides a biological rationale for the use of GeNeuro's temelimab as a novel therapeutic option against the long-term neuropsychiatric syndromes experienced by COVID-19 patients months after their infection.

In December 2021, GeNeuro's **post-COVID** initiative was one of the four projects selected by the Swiss Federal Office of Public Health (FOPH) to receive a grant of 6.7 million Swiss francs (€6.4 million). This grant will co-fund a Phase 2 clinical trial to treat post-COVID patients with severe neurological and psychiatric symptoms with temelimab, GeNeuro's anti-W-ENV antibody. "*This funding from the FOPH comes at a critical moment as it will allows GeNeuro to try to bring a much-needed treatment to the patients affected by neuropsychiatric syndromes post-COVID*," **added Jesús Martin-Garcia**.

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 350 million confirmed cases of COVID-19 worldwide, including more than 150 million in the US 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 a Phase 2 clinical trial expected to start in 1H2022.

Amyotrophic Lateral Disease (ALS)

2021 also brought the results of the joint effort against **ALS** initiated in 2017 by GeNeuro and the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH). This joint NINDS/GeNeuro study has shown a very convincing preclinical proof-of-concept using GeNeuro's anti HERV-K GNK01 monoclonal antibody. A new pathogenic mechanism has been unveiled and characterized, and these results open new perspectives for a biomarker-based therapeutic intervention against sporadic ALS, which represents most cases of this devastating disease affecting 10,000 new patients per year in the US and EU, with a poor prognosis of survival. GeNeuro is actively discussing paths with potential partners for the clinical development of GNK01.

Cash position at December 31, 2021

As of December 31, 2021, GeNeuro had €5.5 million in cash and cash equivalents and no debt. As mentioned above, this does not include the first €3.0 million payment from the Swiss FOPH subsidy, received in January 2022. Based on its planned activities and operations, the Company estimates that its financial resources are sufficient to cover its upcoming deadlines, operational expenses and investments into Q1 2023.

"In these difficult times, securing our runway remains a priority. In July 2021, we completed a € 6 million private placement to extend GeNeuro's financial visibility into 2023, providing us sufficient time to facilitate Phase 3 planning and partnering discussions following the results from our Phase 2 clinical trial of temelimab in MS at the Karolinska Institutet / ASC in Stockholm," **said Miguel Payró, Chief Financial Officer at GeNeuro**. *"Our cash balance at year-end 2021 covers our needs into Q1 2023, excluding our planned post-COVID program which is to be funded by the Swiss FOPH subsidy (of which we have received the first tranche of €3 million in early January 2022) and other dedicated financings."*

Continuing the trend observed during the 2020 financial year, the cash consumption related to GeNeuro's operating and investing activities was reduced to €3.0 million in the second half of 2021, compared to €3.7 million in the first half. Excluding the impact of the planned post-COVID trial, cash consumption is expected to further decrease during 2022 following the completion of the Karolinska clinical trial.

Development of temelimab in Multiple Sclerosis (MS)

Temelimab's one-year Phase 2 trial in MS with the Karolinska Institutet has enrolled 40 patients whose disability progresses without relapses and will document the safety and tolerability of temelimab following higher doses, as well as efficacy based on the latest biomarkers associated with disease progression. Patient recruitment was completed in February 2021 and the last patient visit was completed on January 25, 2022. Top-line results are expected in March 2022.

Development of temelimab in post-COVID

GeNeuro has collaborated with various academic and research centers on the interlink between SARS-CoV-2 and W-ENV. A first publication in the Lancet EBioMedicine in April 2021 showed the systematic presence of the pathogenic protein W-ENV in hospitalized COVID-19 patients and its association with disease severity. Since then, GeNeuro has been involved in numerous academic efforts to understand the role of this W-ENV protein, which is known to have a pro-inflammatory effect and pathogenicity on nervous system cells, in the syndromes suffered by COVID-19 patients, months after the infectious phase has ended. Today, GeNeuro is able to test the presence of W-ENV in the blood of patients suffering from Long-COVID, and is developing temelimab, a specific anti-W-ENV antibody. The clinical trial supported by the FOPH will be a double-blind, randomized, placebo-controlled, biomarker-based clinical study on post-COVID patients with severe neuropsychiatric symptoms that prevent them from continuing their daily and professional activities.

Amyotrophic Lateral Sclerosis (ALS)

Beyond MS and Post-COVID, GeNeuro has continued to advance its preclinical program in ALS in partnership with the NINDS (National Institute of Neurological Disorders and Stroke, part of the U.S. National Institutes of Health). The results of the joint NINDS/GeNeuro study were presented in October 2021 at the American Neurological Association congress, and at "The Lancet Summit: Presymptomatic Prevention and Treatment of Neurodegenerative Diseases" in December 2021. These show in vitro and in vivo the neurotoxic effects specifically mediated by HERV-K ENV, a retroviral envelope protein encoded by a pathogenic member of the HERV-K family of endogenous human retroviruses (HERV-K ENV protein). More importantly, they confirm the neutralizing effects of GeNeuro's novel specific monoclonal anti-HERV-K antibody. Thanks to this research, a new pathogenic mechanism has been unveiled and characterized, and these results open new perspectives for a biomarker-based therapeutic intervention against sporadic ALS.

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 Lyon, France. It has rights to 17 patent families protecting its technology.

For more information, visit: www.geneuro.com

GeNeuro's contacts:

GeNeuro

Jesús Martin-Garcia

Chairman and CEO
+41 22 552 4800
investors@geneuro.com

NewCap (France)

Louis-Victor Delouvrier / Mathilde Bohin
(investors)

+33 1 44 71 98 52
Arthur Rouillé (media)
+33 1 44 71 94 98
geneuro@newcap.eu

Disclaimer

This press release contains certain forward - looking statements and estimates concerning GeNeuro's financial condition, operating results, strategy, projects and future performance and the markets in which it operates. Such forward-looking statements and estimates may be identified by words, such as "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions. They incorporate all topics that are not historical facts. Forward looking statements, forecasts and estimates are based on management's current assumptions and assessment of risks, uncertainties and other factors, known and unknown, which were deemed to be reasonable at the time they were made but which may turn out to be incorrect. Events and outcomes are difficult to predict and depend on factors beyond the company's control. Consequently, the actual results, financial condition, performances and/or achievements of GeNeuro or of the industry may turn out to differ materially from the future results, performances or achievements expressed or implied by these statements, forecasts and estimates. Owing to these uncertainties, no representation is made as to the correctness or fairness of these forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates speak only as of the date on which they are made, and GeNeuro undertakes no obligation to update or revise any of them, whether as a result of new information, future events or otherwise, except as required by law.