Press release

GeNeuro Reports 2022 Full-Year Results and Provides Corporate Update

- **Phase 2 clinical trial of temelimab against neuropsychiatric syndromes of Long-COVID (GNC-501):**
  - **Recruitment ongoing;**
  - **Program further supported by European Investment Bank (EIB) €25m loan**

- **Cash position of €5.6m as of December 31, 2022, offering financial visibility into the third quarter of 2024 including the €7m first tranche of the EIB loan drawn in March 2023**

Geneva, Switzerland, April 5, 2023 – 7:30am CEST – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing novel treatments for neurodegenerative and autoimmune diseases such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and the severe consequences of COVID-19, (PASC, post-COVID or Long-COVID), reports today its full-year results for the year ended December 31, 2022, and provided a corporate update.

With the implementation in March 2023 of the EIB EUR 25 million credit line, backed by InvestEU program, GeNeuro's cash position at year-end 2022 provides good financial visibility into 3Q 2024 based on its current activities.

"2022 was a momentous year for GeNeuro, with the completion of the ProTEct-MS trial, and the launch of our new GNC-501 Phase 2 trial in Long-COVID during the second half. In our main indication, multiple sclerosis, ProTEct-MS has met our key objective of showing that temelimab could bring additional benefits on key markers of neurodegeneration in a population of MS patients already treated with a highly effective anti-inflammatory drug. We are continuing discussions with potential partners to define the best development path combining temelimab and anti-inflammatory treatments to treat relapses and disability progression, the key unmet medical need in MS", **said Jesús Martin-Garcia, CEO of GeNeuro**. *"In addition, GeNeuro has launched the first personalized medicine clinical trial against neuropsychiatric syndromes affecting Long-COVID patients. We have received an important financial backing from the Swiss and European authorities who seek credible potential therapeutic solutions to address a major public health problem which affects millions of patients. We thank the Swiss Federal Office for Public Health and the European Investment Bank for their support."*

"With the 7 million euros drawn down from the first Tranche of the EIB loan complementing our existing cash balance, GeNeuro has operating capital into 3Q 2024," **stated Miguel Payró, Chief Financial Officer at GeNeuro.**

PRODUCT DEVELOPMENT HIGHLIGHTS

Multiple Sclerosis (MS)

On October 27, 2022, GeNeuro presented the primary analysis of the Phase 2 ProTEct-MS study at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2022) Congress in Amsterdam, Netherlands. This study was performed in Stockholm, Sweden, at the Karolinska Institutet's Academic Specialist Center in Stockholm under the leadership of Prof. Fredrik Piehl:

- The primary endpoint of the ProTEct-MS study was met, with results confirming the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with an anti-CD20 treatment, a high-efficacy anti-inflammatory drug. The drug was well tolerated with no treatment related discontinuations, no serious or severe treatment emergent adverse events, and no differences in overall clinical or laboratory safety findings, which meets the primary endpoint of the study.

- Efficacy data, obtained in this patient group already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration, which showed a positive impact of temelimab in preserving neocortical anatomy and myelin integrity. The effect sizes were of comparable magnitude to those previously observed in the prior CHANGE-MS and ANGEL-MS trials in patients without an anti-inflammatory treatment.

- New exploratory data on soluble biomarkers also showed favorable impact on measures of neurodegeneration at one year: the study showed a reduction of GFAP biomarkers in cerebrospinal fluid (CSF). GFAP is a biomarker for astrocytic activation associated with diffuse neuroaxonal damage leading to MS disease progression. The results on these CSF biomarkers confirm the synergistic potential to treat neurodegeneration with temelimab in addition to a high-efficacy anti-inflammatory therapy in MS.

- The analysis of the data now also allows GeNeuro to determine the optimal dose for future temelimab trials in MS, in conjunction with potential partners.

"We are excited by the results of the ProTEct-MS trial as an important step forward for temelimab in its path to treat MS patients in whom disability progresses despite effective control of inflammation and relapses, which is the critical unmet need with current treatment options," **commented Prof. David Leppert, M.D., Chief Medical Officer of GeNeuro.**

Long-COVID

At the end of 2022, GeNeuro launched a Phase 2 trial, called GNC-501, that is evaluating the clinical efficacy of a six-month treatment with temelimab, the anti-W-ENV antibody developed by GeNeuro, on the improvement of cognitive impairment and/or fatigue in long-COVID patients who are positive for the presence of W-ENV protein in their blood. The W-ENV protein was observed in more than 25% of patients with persistent syndromes after having had COVID, as evidenced in a recent publication made available on MedRxiv[1]. This personalized medicine approach could, if the current clinical trial is successful, offer a therapeutic solution to a well identified subset of the millions of patients affected by long-COVID.

GeNeuro's Long-COVID program is supported both by the Swiss Federal Office of Public Health (FOPH), which selected GeNeuro to receive a grant of 6.7 million Swiss francs (€6.7 million), and by the European Investment Bank (EIB), with which GeNeuro entered into a credit agreement for a total amount of up to €25 million, supported by the InvestEU program, of which a first tranche of €7 million was immediately available and was drawn down in March 2023.

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. This problem is now recognized as a major public health emergency, as it is affecting millions of people.

The GNC-501 trial is well underway in Switzerland and GeNeuro is already very pleased to observe that the **W-ENV positivity rate in the patients screened in the trial is within the 25-30% range measured in observational studies before the trial, which confirms the potential to identify and treat a well-defined sub-population within the huge numbers of patients affected by long-COVID**.

The trial has now also started to recruit in Spain and Italy, with Rome and Barcelona having started randomizing patients in March, and five more centers planned to start contributing in April and May in these countries. This represents a four-month delay versus the initial plan, which is mainly due to regulatory and administrative reasons in this complex new indication without established regulatory paths. The Company now expects the first results from the study to be available between 1Q and 2Q 2024.

Amyotrophic Lateral Sclerosis (ALS)

2022 also saw the publication in the leading scientific journal "Annals of Neurology" from the results of the collaboration between GeNeuro and the National Institute of Neurological Disorders and Stroke (NINDS). NINDS is part of the National Institutes of Health (NIH) of the United States. The two publications describe the novel

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[1] *Charvet, Koralnik, Perron et al.: Blood biomarkers-defined subgroups show heterogeneity in post-acute COVID-19 syndrome: a rationale for precision medicine - https://doi.org/10.1101/2023.03.31.23288003*

pathogenic mechanism of HERV-K in sporadic ALS and confirm the rationale and the therapeutic relevance of GeNeuro's antibody to neutralize this neurotoxic protein.

As previously mentioned, GeNeuro's preclinical development program has confirmed the ability to detect HERV-K ENV in sporadic ALS patients and has enabled its anti-HERV-K ENV antibody to be humanized and ready to enter GMP production. The published findings now open the way for precision medicine with a biomarker-based clinical approach, administering GeNeuro's neutralizing antibody only to sporadic ALS patients who are positive to the HERV-K ENV protein.

Amyotrophic lateral sclerosis (ALS), often referred to as Lou Gehrig's disease, is a rapidly progressing neurodegenerative disorder characterized by the destruction of motor neurons leading to progressive muscle paralysis. About 90% of ALS cases occur in patients with no family history of the disease: these cases are known as sporadic ALS, and occur randomly. In the remaining 10% of patients, the disease affects multiple people in the same family with an inherited genetic cause and is called familial ALS. ALS affects approximately 50,000 patients worldwide, with about 10,000 new patients per year in the United States and Europe. GeNeuro continues to discuss paths with potential partners for the clinical development of GNK301.

KEY FINANCIALS 2022

The Board of Directors of GeNeuro reviewed and approved the financial statements for the year ended December 31, 2022. The Statutory Auditors have conducted a review of the annual consolidated financial statements.

GeNeuro Consolidated Income Statement (in thousands of EUR)	**31/12/2022 12 months *Audited***	**31/12/2021 12 months *Audited***
Income	-	-
Research and development expenses		
Research and development expenses	(9,833.2)	(4,886.8)
Subsidies	1,825.8	1,173.5
General and administrative expenses	(3,221.8)	(2,652.4)
Operating loss	**(11,229.2)**	**(6,365.7)**
Net loss for the period	**(12,199.8)**	**(6,817.7)**

	31/12/2022	**31/12/2021**
Basic losses per share (EUR/share)	**(0.51)**	**(0.32)**
Diluted losses per share (EUR/share)	**(0.51)**	**(0.32)**

Due to its development stage, the Company generated no income in 2021 or 2022.

Research & Development expenses increased by €5 million, or 101%, in 2022 compared to 2021, mainly due to the expenses incurred in connection with the Long-COVID program, which led to an increase of €4.3 million (+158%) in studies and research (including the cost of a new manufacturing batch of temelimab to cover the phase 2 trial needs). R&D payroll expense increased €0.7 million, or 59%, as the Company increased its clinical team to manage the Long-COVID trial and as the 2021 figure included €0.3 million of favorable past services cost effect related to the Swiss pension plan curtailment and plan amendment. Reflecting the higher level of studies and research expenses, subsidies (under the form of research tax credits linked to R&D activities), increased by €0.3 million in 2022 over 2021 and other subsidies (which are primarily the accounting charge attributable to the grant portion of the FOPH financing) amounted to EUR 0.5 million. As a result, net R&D expenses increased by 116%, or €4.3 million in 2022 compared to 2021.

General and administrative expenses increased by €0.6 million, or 21%, in 2022, as GeNeuro resumed its travel activities to meet investors and potential partners and as the euro continued to lose ground compared to the Swiss franc, in which the majority of the G&A expenses (notably payroll expense) are incurred. Payroll expense accordingly increased by €0.2 million in 2022 compared to 2021, a year in which a €0.1 million favorable impact was recorded for past services cost effect of the Swiss pension plan curtailment and plan amendment.

Cash and cash equivalents amounted to €5.6 million at December 31, 2022, compared to €5.5 million at December 31, 2021. The €7.7 million capital increase completed in May 2022 and the first two instalments received from the FOPH, totaling €5.2 million, helped offset the Company's cash burn during 2022. The Company's reported cash consumption (i.e., cash outflow from operating activities, given the low level of capital expenditures and investment in intangible assets) was €13.1 million in 2022 compared to €6.8 million in 2021; this €5.3 million increase is mostly due to the higher R&D expenses in 2022, and is in line with the Company's expectations given the launch of the Long-COVID program including the new manufacturing batch of temelimab, completed during 2022. With the EIB €25 million financing recently implemented, from which the Company has already drawn the first tranche of €7 million in March 2023, **the Company's operations are funded into 3Q 2024**. With significant cash outlays in 2022 for the manufacturing of a new batch of temelimab and the start-up expenses of the Long-COVID trial, including advances to suppliers and clinical sites, cash consumption is expected to decrease significantly during 2023.

BUSINESS OUTLOOK

GeNeuro's priorities for 2023 are the completion of patient recruitment for the 6-month treatment Long-COVID trial and its advancement towards completion, and the continued discussions with potential partners to define the best development path combining temelimab and anti-neuroinflammatory treatments to bring the synergistic benefits of temelimab to MS patients. As for ALS, GeNeuro continues to seek specific funding for this program, which would allow to bring this project to an IND within 12-18 months.

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

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