Press release

GeNeuro Reports 2021 Full-Year Results and Provides Corporate Update

- Top-line results of ProTEct-MS clinical trial of temelimab in multiple sclerosis (MS): primary endpoint met, confirmation of synergistic potential to address neurodegeneration
- Clinical trial of temelimab against neuropsychiatric syndromes of post-COVID-19: GeNeuro received in January 2022 the first instalment of €3 million from the Swiss Federal Office of Public Health (FOPH)
- Net cash position of 5.5 million euros as of December 31, 2021, excluding the FOPH payment, offering good financial visibility into the second quarter of 2023

Geneva, Switzerland, April 4, 2022 – 7:30am CEST – 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), reports today its full-year results for the year ended December 31, 2021 and provided a corporate update.

With the completion of the ProTEct-MS trial, GeNeuro's cash position at year-end 2021 provides good financial visibility into Q2-2023 based on its current activities.

"We are excited with the results of the ProTEct-MS trial, which 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", **said Jesús Martin-Garcia, CEO of GeNeuro**. *"GeNeuro will now resume discussions with regulatory authorities and 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. In addition, GeNeuro will continue its development in post-COVID, where we have received a €6.4 million grant from the Swiss government to co-fund a Phase 2 clinical trial in patients suffering from neuropsychiatric syndromes".*

"With the €6 million capital increase completed in July 2021, GeNeuro has operating capital into Q2-2023, providing us with sufficient financial visibility to conduct partnership discussions," **stated Miguel Payró, Chief Financial Officer at GeNeuro.**

PRODUCT DEVELOPMENT HIGHLIGHTS

Multiple Sclerosis (MS)

On March 21, 2022, GeNeuro presented the top-line results from its ProTEct-MS temelimab Phase 2 MS trial performed 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: results confirm the excellent safety profile and tolerability of higher doses of temelimab administered concomitantly with a high-efficacy anti-inflammatory drug;
- Efficacy data, obtained this patient group already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI parameters measuring neurodegeneration; the observed

effect sizes in this new patient population were consistent with the ones shown in the previous CHANGE-MS and ANGEL-MS studies;

- The analysis of the data will also allow GeNeuro to determine the optimal fixed dose for future temelimab trials in MS.
- By targeting fundamental underlying mechanisms of neurodegeneration in MS, i.e. neutralizing microglial-mediated damage, as well as restoring OPC[1] remyelination capacity, temelimab may address progression independent of relapses, the critical unmet need in MS.

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 allows GeNeuro to test what could become a first and much-needed treatment for the millions of 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 Sclerosis (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 GNK301 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 GNK301.

[1] *Oligodendrocyte precursor cell*

KEY FINANCIALS 2021

The Board of Directors of GeNeuro reviewed and approved the financial statements for the year ended December 31, 2021. The Statutory Auditors have conducted a review of the annual consolidated financial statements.

GeNeuro Consolidated Income Statement (in thousands of EUR)	31/12/2021 12 months *Audited*	31/12/2020 12 months *Audited*
Income	-	-
Research and development expenses		
Research and development expenses	(4,886.8)	(4,713.1)
Subsidies	1,173.5	556.0
General and administrative expenses	(2,652.4)	(3,302.0)
Operating loss	**(6,365.7)**	**(7,459.1)**
Net loss for the period	**(6,817.7)**	**(8,962.3)**

	31/12/2021	31/12/2020
Basic losses per share (EUR/share)	**(0.32)**	**(0.45)**
Diluted losses per share (EUR/share)	**(0.32)**	**(0.45)**

Due to its development stage, the Company generated no income in 2021 or 2020.

Research & Development expenses increased by €0.2 million, or 4%, in 2021 compared to 2020, mainly due to the full-year effect of the Karolinska trial and to the expenses incurred in connection with the COVID-19 program, which led to an increase of €0.8 million in studies and research. R&D payroll expense decreased €0.7 million, due to the continued adjustment of the Company's R&D personnel to its current activities, and to €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 €0.5 million in 2021 over 2020. As a result, net R&D expenses decreased by 11%, or €0.4 million in 2021 compared to 2020.

General and administrative expenses decreased by €0.65 million, or 20%, in 2021, as GeNeuro continued its across- the-board cost containment. This decrease is partly attributable, for €0.1 million, to the favorable past services cost effect of the Swiss pension plan curtailment and plan amendment.

Cash and cash equivalents amounted to €5.5 million at December 31, 2021, compared to €6.8 million at December 31, 2020. The decrease is due to the Company's cash burn during 2021, offset by the €6 million capital increase completed in July 2021. 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 €6.8 million in 2021, compared to €7.2 million in 2020; this €0.4 million decrease is mostly due to lower General and administrative expenses in 2021, and is in line with the Company's expectations. **The Company's operations are funded into Q2 2023**, noting that the planned post-COVID program is to be funded by the Swiss FOPH subsidy and other dedicated financings. Excluding the impact of this planned post-COVID trial, cash consumption is expected to decrease significantly during 2022 following the completion of the Karolinska clinical trial.

BUSINESS OUTLOOK

Following the presentation of top-line results from the Karolinska trial, GeNeuro's priorities for 2022 are to resume discussions with regulatory authorities and 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. In addition, GeNeuro remains committed to pursuing its programs in Post-COVID and ALS; in addition to the €6.4 million grant received from the Swiss FOPH, the Company continues to seek dedicated financing to launch its Phase 2 in Post-COVID and to finalize its pre-clinical program in ALS, seeking to bring this project to an IND by early 2023.

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	**NewCap (France)**
Jesús Martin-Garcia Chairman and CEO +41 22 552 4800 investors@geneuro.com	Mathilde Bohin / Louis-Victor Delouvrier (investors) +33 1 44 71 98 52 Arthur Rouillé (media) +33 1 44 71 94 98 geneuro@newcap.eu

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