

GeNeuro Reports 2022 Half-Year Results and Provides Corporate Update

- **Strong financial position and visibility**
 - Cash position of €11 million
 - Financing of activities assured into Q4 2023

- **Starting new Phase II clinical trial evaluating temelimab in patients with “Long-COVID”**
 - The personalized medicine trial will evaluate temelimab as a Disease Modifying Therapy in long-COVID patients suffering from severe neurological and psychiatric symptoms and who are positive for the presence of the pathogenic W-ENV protein in their blood

- **New data on the link between HERV-K ENV and ALS**
 - Two studies on ALS (Amyotrophic Lateral Sclerosis) published in Annals of Neurology demonstrate the neurotoxic role of human endogenous retrovirus envelope protein (HERV-K/HML-2 ENV) and the rationale for targeted therapy with GeNeuro’s new specific antibody

Geneva, Switzerland, September 29, 2022, at 6:30pm CEST – 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 reported its half-year financial results for the period ending June 30, 2022 and provided a corporate update.

Key Financials

On September 29, 2022, the Board of Directors of GeNeuro reviewed and approved the financial statements for the six-month period ended June 30, 2022. The auditors have conducted a review of the condensed consolidated interim financial statements. The half-year financial report is available in the Investors section on www.geneuro.com.

“In March 2022, we presented the successful ProTEct-MS Phase II top-line results, 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. GeNeuro has resumed 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,” said Jesús Martin-Garcia, CEO of GeNeuro. “The successful completion of the May 2022 capital increase provides GeNeuro with the means to complete its post-COVID program with temelimab. This trial, which has now started, will be the first personalized therapeutic approach in this indication, as the study will only enroll patients who are positive to the pathogenic W-ENV protein.

“Thanks to the capital increase of May 2022 and a cash balance of €11 million at the end of the semester, our financial visibility extends into Q4 2023 taking into account all costs related to the Long-COVID trial” , said Miguel Payró, Chief Financial Officer at GeNeuro. “The financial results for the first half of 2022, which are largely in line with our expectations, reflect the increase in activity in connection with our long-COVID trial. Indeed, during the first half of 2022 our gross R&D expenses increased by 75% compared to

the same period of 2021, primarily due to the launch of a new production of temelimab, our lead drug candidate, in order to meet the needs of the new GNC-501 Phase 2 clinical trial treating long-COVID patients with severe neurological and psychiatric symptoms with temelimab. At the same time, the amount of subsidies and grants more than doubled over the period, to €1.2 million. As for our general and administrative expenses, thanks to our continuing cost containment efforts, these have increased by only 4%, largely thanks to a decrease of 12% in our administrative payroll expense. Overall, due to the increase in our clinical activities, the operating loss has increased from €3.5m to €4.9m in 1H 2022. This loss is in line with our expectations”.

Cash burn from operating and investing activities in 1H 2022 was €2.5m, compared to €3.7m in 1H 2021. This is largely due to the payment during 1Q 2022 of the first instalment from the Swiss Federal Office for Public Health (FOPH) subsidy for the long-COVID trial. Taking into account the expected increase in R&D expenses related to the start of this trial, the cash burn for the full year is now estimated to be approximately €12.5m on a gross basis, and €6m when taking into account the FOPH subsidy instalments and the 2021 French Research Tax Credit, compared to €6.8m net for 2021.

Condensed Consolidated Income Statement (in thousands of EUR) <i>subject to a limited review</i>	June 30, 2022 6 months	June 30, 2021 6 months
Income	-	-
Research & Development expenses	(3,402)	(2,080)
R&D expenses	(4,651)	(2,664)
Subsidies	1,249	584
General & administrative expenses	(1,487)	(1,426)
Operating loss	(4,889)	(3,506)
Net loss for the period	(5,675)	(3,403)
Basic loss per share (EUR)	(0.25)	(0.17)
Diluted loss per share (EUR)	(0.25)	(0.17)
Cash outflow from operations	(2,519)	(3,703)
Cash at period end	10,999	2,961

As in the prior year and as expected, **no Income** was recognized during 1H 2022.

Research & Development expenses increased by 75% on a gross (before subsidies) basis, compared to the first half of 2021, due to expenses related to the preparation of the long-COVID trial and the completion of the ProTEct-MS study of temelimab in MS at the Karolinska Institutet in Stockholm. Costs for studies and research more than doubled from €1,555K to €3,236K (+108%), whereas other research and development costs showed either decreases or much slower increases; in particular, personnel costs increased from €783K to €1,023K due to the build-up in clinical staff for the long-COVID trial. Reflecting the increase in R&D activities, subsidies also increased from €584K to €1,249K, with net R&D costs increasing by 64%.

General and administrative expenses increased by 4% in 1H 2022, following a 17% decrease in 1H 2021. Among the key expense categories to increase were travel expenses (+€89K), as COVID-related restrictions were lifted; and professional fees (+€64K). The Company continued to control its administrative staff costs, which decreased by €97K (-12%) due to lower variable compensation. Share-based payments recorded an expense of €75K compared to €54K in 1H 2021.

Financial expenses increased from €103K in 1H 2021 to €787K in 1H 2022, which includes €589K of share-based expense related to the May 2022 capital increase having been realized through a private placement at a 7% discount to the market price.

As a result, the Company recorded a net loss of €5,675K in 1H 2022, compared to a net loss of €3.4m in 1H 2021, in line with management's expectations.

Cash and cash equivalents amounted to €11m at 30 June 2022, compared to €5.5m at 31 December 2021. This reflects the €3m first instalment payment from the Swiss FOPH subsidy contract for the Long-COVID trial as well as the €7.7m capital increase completed in May 2022 through a private placement reserved for

institutional investors. In addition, the Company entered into an unsecured 3-year €1m bank loan with a major French bank. Cash burn in 1H 2022 was €2.5m, compared to €3.7m in 1H 2021; taking into account all the costs of the long-COVID clinical trial, cash burn for the full year is now estimated to be approximately €12.5m on a gross basis, and €6m when taking into account the FOPH subsidy instalments and the 2021 French Research Tax Credit (received in September 2022), compared to €6.8m net for 2021.

Business and Financial Outlook

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. 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 a high-efficacy anti-inflammatory drug.

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

By targeting fundamental underlying mechanisms of neurodegeneration in MS, i.e. neutralizing microglial-mediated damage, as well as restoring OPC¹ remyelination capacity, temelimab may address progression independent of relapses, the critical unmet need in MS.

Long-COVID: the expression of the pathogenic W-ENV protein triggered by the SARS-CoV-2 infection, continuing long after the acute COVID-19 phase has been resolved, is suspected to have a major role in the persistence of inflammation in many long-COVID patients, and may explain many of the nervous system disorders that patients experience, such as cognitive losses and fatigue. GeNeuro has started a 6-month multicentre personalized medicine trial, co-financed by the Swiss FOPH, to evaluate temelimab as a Disease Modifying Therapy in long-COVID patients suffering from severe neurological and psychiatric symptoms. The study will recruit 200 patients who are positive for the presence of the pathogenic W-ENV protein in their blood.

Amyotrophic lateral sclerosis: as previously reported, two joint publications in the leading scientific journal "Annals of Neurology" presented the results of the collaboration between GeNeuro and the US National Institute of Neurological Disorders and Stroke (NINDS), which is part of the National Institutes of Health (NIH) of the United States. The two publications describe the novel pathogenic mechanism of HERV-K in sporadic ALS and confirm the rationale for the therapeutic relevance of GeNeuro's antibody to neutralize this neurotoxic protein. 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. As previously mentioned, GeNeuro continues to actively discuss paths with potential partners for the clinical development of GNK301.

Financial visibility until end 2023: thanks to the capital increase completed in May 2022, the Company's cash provides financial visibility into Q4 2023, including the completion of the long-COVID clinical trial.

Other highlights and post-closing events

On August 30, 2022, the Company announced the joint publications in the leading scientific journal "Annals of Neurology" of the results of the collaboration between GeNeuro and the National Institute of Neurological Disorders and Stroke (NINDS).

Next events

Investor Access Event: October 6-7, 2022 – Paris

ECTRIMS: oral presentation of ProTECT-MS results, October 27, 2022 - Amsterdam

¹ Oligodendrocyte precursor cell

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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