Press release

GeNeuro Reports 2023 Half-Year Results and Provides Corporate Update

- **Strong financial position and visibility**
  - Cash position of €7.4 million
  - Financing of activities assured into Q3 2024

- **Ongoing Phase II clinical trial evaluating temelimab in patients with "Long-COVID"**
  - The personalized medicine trial evaluates 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 further substantiating the neuropathogenic role of the HERV-W protein in MS**
  - Study published in "Proceedings of the National Academy of Sciences of the United States of America" (PNAS) confirms that the expression of the HERV-W Env protein (W-Env) causes a neurodegenerative environment, through the fostering of demyelination and the reduction of remyelination, which may explain the long-term neurodegeneration suffered by MS patients

- **€25 million credit line with the European Investment Bank ("EIB"), backed by InvestEU, to support clinical developments against long-COVID**
  - First tranche of €7 million drawn in March 2023 to support the Phase 2 clinical trial in long-COVID.

Geneva, Switzerland, October 2, 2023, at 7:30am 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, 2023 and provided a corporate update.

Key Financials

On September 26, 2023, the Board of Directors of GeNeuro reviewed and approved the financial statements for the six-month period ended June 30, 2023. 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.

"GeNeuro is currently running the first biomarker-based medicine clinical trial against neuropsychiatric syndromes affecting Long-COVID patients. This ground-breaking trial benefits from the important financial backing by the Swiss and European authorities who seek credible potential therapeutic solutions to address a major public health problem which affects millions of patients. As a reminder, in March 2023 GeNeuro entered into a €25 million credit agreement with the European Investment Bank ("EIB"), supported by the InvestEU program. With the recent opening of new sites in Madrid, Spain, and in Rome,

Italy, the clinical trial now counts fourteen sites recruiting patients in Switzerland, Spain and Italy, and we aim to present the top-line results in Q2 2024," **said Jesús Martin-Garcia, CEO of GeNeuro**. *"Following the presentation of our successful ProTEct-MS Phase II results in MS, we continue our 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."*

"As we had previously announced, our available cash resources provide GeNeuro with financial visibility into Q3 2024", **said Miguel Payró, Chief Financial Officer at GeNeuro.** *"The financial results for the first half of 2023, which are largely in line with our expectations, reflect the significant increase in activity in connection with our long-COVID trial. Indeed, during the first half of 2023 our gross R&D expenses increased by 30% compared to the same period of 2022, due to the ramp-up of our 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 has reduced from €1.2 million to €0.7 million, as the bulk of our R&D activities are conducted by the Group's Swiss parent. As for our general and administrative expenses, they have increased by 17%, largely due to the effect of inflation on a number of cost items, to the continued decrease of the euro vs. the Swiss franc (minus 4.5% during 1H 2023) and to a resumption of travel activities to meet investors and partners. Overall, the operating loss has increased from €4.9m to €7.1m in 1H 2023. This loss is broadly in line with our expectations. Thanks to the drawdown in March of the first tranche of €7.0 million from the EIB financing for our Long-COVID program, our financial visibility is confirmed into 3Q 2024."*

Cash burn from operating and investing activities in 1H 2023 was €4.7m, compared to €2.5m in 1H 2022, which benefited from the collection of €3.0 million from the first instalment from the Swiss Federal Office for Public Health (FOPH) subsidy for the long-COVID trial. Excluding this instalment from the 1H 2022 numbers, cash burn was lower by €0.8m during the first half of 1H 2023. The Company expects its cash consumption to remain stable during the second half of 2023 as the long-COVID clinical trial advances.

Condensed Consolidated Income Statement (in thousands of EUR) *subject to a limited review*	**June 30, 2023 6 months**	**June 30, 2022 6 months**
Income	**-**	**-**
Research & Development expenses	**(5,316)**	**(3,402)**
R&D expenses	(6,035)	(4,651)
Subsidies	719	1,249
General & administrative expenses	**(1,747)**	**(1,487)**
Operating loss	**(7,063)**	**(4,889)**
Net loss for the period	**(6,862)**	**(5,675)**
Basic loss per share (EUR)	**(0.28)**	**(0.25)**
Diluted loss per share (EUR)	**(0.28)**	**(0.25)**
Cash outflow from operations	**(4,720)**	**(2,519)**
Cash at period end	**7,398**	**10,999**

As in the prior year and as expected, **no Income** was recognized during 1H 2023.

Research & Development expenses increased by 30% on a gross (before subsidies) basis, compared to the first half of 2022, due to expenses for the long-COVID trial. Costs for studies and research increased 40% from €3,236K to €4,497K, whereas other research and development costs were essentially flat; in particular, personnel costs increased 6% from €1,023K to €1,089K. As the bulk of the Company's GNC-501 Phase 2 clinical trial activities are conducted out of the Swiss parent and are therefore not eligible for French Research Tax Credit, research tax credits decreased from €968K in the first half of 2022 to € 270K, whereas other subsidies increased from €281K to €450K, including €70K from the European Union HERVCOV grant and €240K of subsidies accounted for in connection with the Swiss FOPH grant.

General and administrative expenses increased by 17% in 1H 2023. Among the key expense categories to increase were travel expenses (+€48K), as COVID-related restrictions were lifted; and professional fees (+€46K). Due to inflation-related salary increases and due to the continued weakening of 4.5% of the EUR vs the Swiss franc (the currency in which approximately three quarters of the general and administrative

expenses are incurred), payroll expense increased from €713K to €858K. Share-based payment expenses were €102K compared to €75K in 1H 2022.

Financial expenses decreased to €452K in 1H 2023 from €967K in 1H 2022, which included €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. **Financial income** increased from €180K to €656K, thanks to a €571K favorable change in the fair value of derivatives issued to the EIB in connection with its loan, resulting in a net financial income of €204K in 1H 2023 compared to a net financial expense of €787K in 1H 2022.

As a result, the Company recorded a net loss of €6,862K in 1H 2023 compared to 5,675K in 1H 2022, in line with management's expectations.

Cash and cash equivalents amounted to €7.4m at 30 June 2023, compared to €5.6m at 31 December 2022. This reflects the €7m gross proceeds from the drawdown of the first tranche of the EIB loan. Cash burn in 1H 2023 was €4.7m, compared to €2.5m in 1H 2022, which benefited from the collection of €3.0 million from the first instalment from the Swiss FOPH subsidy for the long-COVID trial. Excluding this instalment from the 1H 2022 numbers, cash burn was lower by €0.8m during the first half of 1H 2023. The Company expects cash burn for the full year to be approximately €10m on a gross basis (excluding the effect of financings and grants), compared to €16m in 2022.

Business and Financial Outlook

Multiple Sclerosis (MS): in October 2022, GeNeuro presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2022) Congress in Amsterdam, Netherlands, the primary analysis of 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 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.

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 in MS. This approach is supported by the recent study published in PNAS that confirms that the expression of W-Env causes a neurodegenerative environment, through the fostering of demyelination and the reduction of remyelination, which may explain the long-term neurodegeneration suffered by MS patients. GeNeuro is thus continuing discussions with potential partners to define the best development pathway combining temelimab and anti-inflammatory treatments.

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. 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.

[1] *Oligodendrocyte precursor cell*

GeNeuro's Long-COVID program is supported both by the Swiss FOPH, which selected GeNeuro to receive a grant of 6.7 million Swiss francs (€6.7 million), and by the 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, Spain and Italy and GeNeuro is already very pleased to observe that the W-ENV positivity rate in the patients screened in the trial is, at 30%+, above the 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 is now actively recruiting in Switzerland, Spain and Italy, with fourteen centers. The Company now expects the first results from the study to be available in 2Q 2024.

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 into Q3 2024: the Company's cash provides financial visibility into Q3 2024, after the expected completion of the long-COVID clinical trial.

Other highlights and post-closing events

On September 27, 2023, the Company announced the publication in published in the journal "Proceedings of the National Academy of Sciences of the United States of America" (PNAS) of a new study further substantiating the neuropathogenic role of the HERV-W protein in MS, with data confirming that the expression of the HERV-W Env protein (W-Env) causes a neurodegenerative environment, through the fostering of demyelination and the reduction of remyelination, which may explain the long-term neurodegeneration suffered by MS patients.

Next events

BioFuture : October 4-6 2023 - New York
Investor Access Event: October 9-10, 2023 – Paris

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 18 patent families protecting its technology.

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

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