

GeNeuro Reports 2023 Full-Year Results and Provides Corporate Update

- **Phase 2 clinical trial of temelimab against neuropsychiatric syndromes of Post-COVID (GNC-501):**
 - Recruitment completed in November 2023;
 - Topline results planned for end of June 2024.
- **Cash position of €2.8m as of December 31, 2023, including the €1m pre-financing of Research tax Credit received in January 2024**
- **Financial visibility into the third quarter of 2024 taking into account the €5m capital increase completed in Q1 2024**

Geneva, Switzerland, April 30, 2024 – 6.30pm CEST – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company focused on halting the progression of neurodegenerative and autoimmune diseases such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and the post-acute sequelae of COVID-19 (PASC, long COVID or post-COVID), reported today its full-year results for the year ended December 31, 2023, and provided a corporate update.

With the completion in February 2024 of a EUR 5 million capital increase, GeNeuro's cash position provides financial visibility into 3Q 2024 based on its current activities.

“2023 was an important year for GeNeuro, with the completion of patient recruitment of our GNC-501 Phase 2 trial evaluating temelimab against post-COVID. GeNeuro is conducting the first personalized medicine clinical trial against neuropsychiatric syndromes affecting Post-COVID patients, and we are now looking forward to the topline results at the end of June 2024. This trial benefits from an important financial backing from the Swiss and European authorities who seek potential therapeutic solutions to address a major public health problem which affects millions of patients”, said Jesús Martin-Garcia, CEO of GeNeuro. “In our other main indication, multiple sclerosis, we have continued 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.”

PRODUCT DEVELOPMENT HIGHLIGHTS

Multiple Sclerosis (MS)

In MS, GeNeuro is focused on combating neurodegeneration. The Company has completed three Phase 2 clinical trials, the latest, which was completed in 2022, in patients with relapsing-remitting MS under treatment with rituximab, a monoclonal anti-CD20 antibody that is highly potent and effective against the acute course of the disease (inflammatory relapses and brain lesion formation). The results from this study were presented in October 2022 at theECTRIMS scientific congress and have shown that 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; in addition, efficacy data, obtained in these patients already effectively treated against inflammation, showed that temelimab has a favorable impact on key MRI and liquid measures of neurodegeneration. Given the high costs of the international clinical trials necessary to confirm efficacy and register a product in MS with both the FDA and the EMA, which the Company estimates to exceed €100 million, continued development in MS requires a partnership and GeNeuro has continued discussions with potential partners to define the best development path for combining existing anti-inflammatory treatments, to treat relapses, with temelimab to treat neurodegeneration and disability progression, the key unmet medical need in MS.

Post-COVID

GeNeuro is currently running a Phase 2 clinical trial with temelimab to treat, during six months, patients suffering from severe neurological and psychiatric (“neuropsychiatric”) symptoms post-COVID. GeNeuro has completed the recruitment of 203 patients in this clinical trial in November 2023, and is expecting its results for June 2024. This trial, partly financed by the Swiss Federal Office of Public Health (“FOPH”) through a grant of CHF 6.7 million (€7 million) by the European Investment Bank through a €7 million venture debt financing, results from research conducted following the COVID-19 pandemic and the emergence of post-COVID, leading to published results that (1) evidenced the presence of W-ENV in the serum of patients suffering from acute COVID; (2) evidenced that SARS-CoV-2 is able to induce the in vitro expression of W-ENV in human blood cells of approximately 20% of the samples of healthy volunteers; and (3) have shown that the W-ENV protein is present in more than 25% of post- COVID patients. This placebo-controlled double-blind study is the largest one to date in this indication and the only one based on a precision medicine approach, as each enrolled patient has been tested positively for the presence of W-ENV. This study includes numerous clinical endpoints, including the primary endpoint which is the measure of fatigue in the patients; as there is today no available disease-modifying therapy against post-COVID syndromes, positive results could lead to accelerated processes to make temelimab rapidly available to the millions of patients affected by severe post-COVID in Europe and in the USA.

Amyotrophic Lateral Sclerosis (ALS)

GeNeuro’s pre-clinical program in ALS, developed in partnership with the NINDS in the United States, has achieved a very strong preclinical proof of concept, published in major scientific publications such as Annals of Neurology, and confirmed by third-party research groups.; The continuation of the Company program towards IND submission, with a timing target of 18 months after such fundraising, requires a specific financing estimated at €7 million.

KEY FINANCIALS 2023

The Board of Directors of GeNeuro reviewed and approved the financial statements for the year ended December 31, 2023. The Statutory Auditors have conducted a review of the annual consolidated financial statements.

GeNeuro Consolidated Income Statement (in thousands of EUR)	31/12/2023 12 months Audited	31/12/2022 12 months Audited
Income	-	-
Research and development expenses		
Research and development expenses	(12,492.1)	(9,833.2)
Subsidies	1,143.4	1,825.8
General and administrative expenses	(3,008.6)	(3,221.8)
Operating loss	(14,357.3)	(11,229.2)
Net loss for the period	(14,757.0)	(12,199.8)
	31/12/2023	31/12/2022
Basic losses per share (EUR/share)	(0.59)	(0.51)
Diluted losses per share (EUR/share)	(0.59)	(0.51)

Due to its development stage, the Company generated no income in 2023 or 2022.

Research & Development expenses increased by €2.7 million in 2023 compared to 2022, due to the expenses incurred in connection with the Post-COVID program, which led to an increase of €2.6 million in studies and research in connection with the GNC-501 clinical trial. R&D payroll expense increased by €0.1 million and other costs remained broadly in line with the levels observed in 2022. Despite the higher level of studies and research expenses, subsidies (under the form of research tax credits linked to R&D activities) decreased by €0.8 million in 2023 over 2022 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; other subsidies increased from K€ 509 to K€ 588; these other subsidies include K€ 140 of debt cancellation from Bpifrance in connection with the K€ 200 reimbursable advance that had been granted to GeNeuro Innovation SAS in 2011, K€ 182 from the European Union HERVCOV grant and K€ 265 of subsidies accounted for in connection with the Swiss FOPH grant. As a result, net R&D expenses increased by 42%, or €3.3 million in 2022 compared to 2021.

General and administrative expenses decreased by €0.2 million in 2023, as GeNeuro replaced the cash bonuses for staff and management by stock options, resulting in a reduction of payroll expense by €0.2 million in 2023 compared to 2022.

Cash and cash equivalents amounted to €1.8 million at December 31, 2023, compared to €5.6 million at December 31, 2022. In addition, in January 2024 the Company implemented a €1 million bank non-recourse pre-financing for the 2022 Research Tax Credit and completed in February 2024 a €5 million capital increase. 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 €10.1 million in 2023 compared to €13.1 million in 2022; this €3.0 million decrease was due primarily to the positive €3.9 million impact from the change in working capital in 2023 compared to a negative impact of €1.9 million in 2022, as a result of higher trade payables and accrued liabilities and the reduction of other current assets. With the GNC-501 clinical trial ending in June 2024, cash consumption is expected to decrease significantly during 2024.

BUSINESS OUTLOOK

GeNeuro's priorities for 2024 are focused on the completion of the GNC-501 trial, with topline results planned for end of June 2024 and, subject to positive results, the preparation of a Phase 3 and/or of the temporary marketing authorization. In MS, GeNeuro will continue 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 18 months.

2024 FIRST-QUARTER FINANCIAL INFORMATION

On March 31, 2024, the Company had a cash position of €2.9 million. This includes the net proceeds of € 5 million capital increase and the cash consumption for the quarter. The available cash resources provide GeNeuro with good visibility into mid Q3-2024.

For Q1 2024, the cash consumption related to GeNeuro's operating and investing activities was €2.9 million, compared to €3.0 million for the same period of 2023. The Q1 2024 cash consumption included the reduction of working capital in connection with trade payables for the Phase 2 clinical trial in Post-COVID. The Company expects its quarterly cash consumption to decrease during 2024 as the post-COVID clinical trial will be completed in June 2024.

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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