Press release

GeNeuro Reports 2021 Half-Year Results and Provides Corporate Update

- **Strong financial position and visibility:**
  - Net cash position of €9.2m pro forma, following the capital increase of early July 2021
  - Financing of activities assured until the end of 2022

- **ProTEct-MS clinical trial results expected in Q1 2022**:
  - Completion of enrolment in February 2021 of the Phase 2 trial of temelimab in multiple sclerosis at the Karolinska Institutet/ Academic Specialist Center (ASC), in Stockholm, enabling to confirm the timing of results.

- **New data on the link between HERV-W ENV and COVID-19:**
  - Publication in the *Lancet's EBioMedicine* of data on the detection of the pathogenic protein HERV-W ENV in the blood of hospitalized patients with COVID-19, and on the link between the level of expression of this protein and the severity of the disease
  - Presentation of data supporting a biological rationale linking HERV-W ENV to long-term neuropsychiatric symptoms affecting a significant subset of long-COVID patients
  - These findings pave the way for clinical trials of temelimab for long-COVID patients, for which non-dilutive funding applications are underway.

Geneva, Switzerland, September 29, 2021 at 7:00pm CEST – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for neurodegenerative and autoimmune diseases, such as multiple sclerosis (MS), today reported its half-year financial results for the period ending June 30, 2021 and provided a corporate update.

Key Financials

On September 29, 2021, the Board of Directors of GeNeuro reviewed and approved the financial statements for the six-month period ended June 30, 2021. 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.

"*The completion of enrolment in our ProTEct-MS study, announced in February 2021, allows us to confirm the Q1 2022 timeframe for its results. If successful, GeNeuro will have a product that specifically targets neurodegeneration in MS, which affects 80% of patients whose disability progresses despite effective treatments for inflammatory relapses. With the fundraising completed in July, GeNeuro will be in a very good position to conduct strategic discussions for Phase 3,*" **said Jesús Martin-Garcia, CEO of GeNeuro**. "*The first half of 2021 has also been very rich in scientific discoveries in the field of endogenous retroviruses, in which GeNeuro is the leader. The link with HERV-W ENV, the pathogenic protein targeted by temelimab, during the infectious phase of COVID-19 was published in the Lancet's EBioMedicine in April. The data obtained and reported since then indicate that* ***the neuropsychiatric symptomatology observed in patients with "long-COVID" syndromes may be due to this activation of HERV-W ENV expression by SARS-CoV-2, and its persistence long after the acute phase,*** *opening the door to therapeutic trials with temelimab against long-COVID*".

"The financial results for the first half of 2021 are largely in line with our expectations. Our gross R&D expenses increased by 20% compared to the first half of 2020, which was notably marked by the 3-month delay in the start of our new clinical trial at Karolinska caused by the COVID-19 pandemic. At the same time, the increase in grants received by GeNeuro reduces the increase in net R&D expenses to 4%. In addition, thanks to our ongoing cost containment efforts, our general and administrative expenses decreased by 17%. Overall, we have reduced the operating loss by 6% to €3.5m from €3.7m in H1 2020. This loss is in line with our expectations," **said Miguel Payró, Chief Financial Officer at GeNeuro**.

Cash burn from operating and investing activities in Q2 2021 was €1.6m, compared to €2.1m in Q1 2021. The cash burn in Q2 2021 was slightly higher than the company's expectations, mainly due to charges related to the new COVID-19 project and the delay in the receipt of the 2020 Research Tax Credit, initially expected in Q2 2021 but finally received in Q3 2021. Taking into account the expenses related to the ProTEct-MS clinical trial, the COVID-19 project and the preparation of Phase 3 in MS, the cash burn for the full year is now estimated at approximately €6.3m, compared to €5.2m reported in April 2021 and €7.2m in 2020.

Condensed Consolidated Income Statement (in thousands of EUR)	**June 30, 2021 6 months** subject to a limited review	**June 30, 2020 6 months** subject to a limited review
Income	**-**	**-**
Research & Development expenses	**(2,080)**	**(1,997)**
R&D expenses	(2,664)	(2,226)
Subsidies	584	230
General & administrative expenses	**(1,426)**	**(1,718)**
Operating loss	**(3,506)**	**(3,715)**
Net loss for the period	**(3,403)**	**(3,948)**
Basic loss per share (EUR)	**(0.17)**	**(0.20)**
Diluted loss per share (EUR)	**(0.17)**	**(0.20)**
Cash outflow from operations	**(3,703)**	**(3,795)**
Cash at period end	**2,961**	**10,492**

As in the prior year and as expected, **no Income** was recognized during H1 2021.

Research & Development expenses increased by 20% compared to the first half of 2020, due to expenses related to the ProTEct-MS study of temelimab in MS at the Karolinska Institutet in Stockholm; indeed, this study started in June 2020 but saw its recruitment finalised in February 2021, which means that costs for the first half of 2021 therefore reflect a "cruising speed" for most of the period. Clinical trial costs thus almost doubled from €815K to €1,555K, or +90%, while other research and development costs were stable or decreasing, notably personnel costs which were again reduced from €1.0m to €783K due to a reduction in staff in the second half of 2020. Furthermore, as subsidies also increased, net R&D costs ultimately increased by only 4%.

General and administrative expenses decreased by 17% in H1 2021, following a 4% decrease in H1 2020, due to continued cost containment efforts, and thus totalled €1.4m compared to €1.7m in the comparable period. The Company continued to control its administrative staff costs (-4%), and recorded a strong decrease in travel expenses (-€69K, or 81%, due to the continued restrictions on travel and congresses imposed during the COVID-19 pandemic) as well as in professional fees, which were down €210K (-38%) due to strict cost control. Share-based payments recorded an expense of €54K compared to €36K in H1 2020.

As a result, the Company recorded a net loss down 15% to €3.4m in H1 2021, compared to a net loss of €3.9m in H1 2020, in line with management's expectations.

Cash and cash equivalents amounted to €3.0m at 30 June 2021 compared to €6.8m at 31 December 2020. The Company completed a €6.0m capital increase on 13 July 2021 through a private placement reserved for institutional investors, bringing its pro forma cash position to €9.2m including the net proceeds of this transaction and the Reseach Tax Credit received in August 2021. Cash burn in H1 2021 was €3.7m compared to €3.8m in H1 2020; taking into account all the costs of the ProTEct-MS clinical trial, expenses related to the COVID-19 project and the preparation of Phase 3 in MS, cash burn for the full year is estimated at approximately €6.3m, compared to €5.2m reported in April 2021 and compared to €7.2m in 2020.

Business and Financial Outlook

ProTEct-MS Phase 2 trial with temelimab in MS at Karolinska Institutet: The Company announced on 18 February 2021 that it had finalised the recruitment of patients for this study, having made up half of the delay caused by the COVID-19 pandemic. With the Data and Safety Monitoring Board having approved the continuation of the ProTEct-MS study on 2 March 2021 and confirming the good tolerability of the higher doses up to 54 mg/kg, results are now expected in Q1 2022. For patients who have completed the study, GeNeuro has initiated an extension of the clinical trial that offers patients the opportunity to continue receiving temelimab.

COVID-19: Following the publication in the Lancet's EBioMedicine on 15 April 2021 that a team of researchers had detected the pathogenic protein HERV-W ENV in hospitalized patients with COVID-19 and had established a link between its expression level and the severity of the disease course, GeNeuro has expanded its work in this indication and renewed its collaboration agreement with CIRI and its extension to post-COVID syndromes. On 5 July 2021, GeNeuro presented data supporting the pathogenic role of the endogenous retroviral protein HERV-W ENV in post-COVID neuropsychiatric syndromes, and announced a collaboration with the FondaMental Foundation to accelerate the development of diagnostic and therapeutic options for patients. On September 24, 2021, GeNeuro also announced a research collaboration with Northwestern University aiming to confirm evidence of the expression of human endogenous retrovirus W envelope protein (HERV-W ENV) in long-haul COVID patients, and identify affected patients who may benefit from a treatment with GeNeuro's temelimab.

Amyotrophic lateral sclerosis: As previously reported, GeNeuro is currently finalising its preclinical programme in amyotrophic lateral sclerosis (ALS), in partnership with the National Institute of Neurological Disorders and Stroke (NINDS, part of the US National Institutes of Health). Preparation for GMP pre-production will be completed in H2 2021, paving the way for partnership discussions for its novel anti-HERV-K ENV antibody in this indication.

Financial visibility until end 2022: Thanks to the capital increase completed in July 2021, the Company's cash provides financial visibility until the end of 2022 and provides sufficient time for strategic discussions following the results of the ProTEct-MS clinical trial of temelimab in MS.

Other highlights and post-closing events

As previously reported, the Company completed a €6.0m capital increase on 13 July 2021; GeNeuro also presented data in early July supporting the pathogenic role of the endogenous retroviral protein HERV-W ENV in long-COVID neuropsychiatric syndromes, and announced collaborations with the FondaMental Foundation and with Northwestern University to accelerate the development of diagnostic and therapeutic options for long-COVID patients.

At the end of September 2021, Dr. Jean-François Arrighi, GeNeuro's Chief Development Officer, will step down and will be replaced by Dr. Alois Lang, who previously held this position from 2008 to 2018.

In addition, GeNeuro announced on July 15, 2021 the publication in Multiple Sclerosis Journal of the results of the CHANGE-MS and ANGEL-MS clinical trials evaluating temelimab in multiple sclerosis.

Next financial event

MidCap Event: October 21-22 2021 – 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 17 patent families protecting its technology.

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

Contacts:

GeNeuro

Jesús Martin-Garcia

Chairman and CEO
+41 22 552 4800
investors@geneuro.com

NewCap (France)

Louis-Victor Delouvrier / Mathilde Bohin (investors)

+33 1 44 71 98 52
Arthur Rouillé (media)
+33 1 44 71 94 98
geneuro@newcap.eu

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