GeNeuro: financial information and business update for the first quarter 2018

- Q1 2018 operating revenues of €2.9 million (+ 84% vs. Q1 2017)
- €20.0 million cash at March 31, 2018
- Promising Phase IIb results in multiple sclerosis, demonstrating a major impact on three key neuroprotection markers
- Orphan Drug designation received from the FDA in chronic inflammatory demyelinating polyneuropathy (CIDP)

Geneva, Switzerland, May 9, 2018 – 7:30am CEST – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurological and autoimmune diseases, including multiple sclerosis (MS) and type 1 diabetes (T1D), today issued a business update and reported on its cash position and 2018 first-quarter revenues.

2018 First-quarter financial information

During the first three months of FY 2018, GeNeuro recorded €2.9 million in operating revenues, an 84% increase compared to the same period in 2017. These operating revenues were recognized in respect of milestone payments already paid by its partner Servier in connection with ongoing clinical trials of GNbAC11, its lead drug candidate. Given the recent completion of the CHANGE-MS Phase IIb clinical trial in the MS indication, the results of which were published on March 26, 2018, the Company plans to recognize during FY 2018 the last revenues in relation to the milestone payments received in respect of this trial.

Cash used for operating and investing activities amounted to €6.1 million in the first quarter 2018, down from €7.2 million in the first quarter 2017. The Q1 2018 outflow amount included €3.5 million in payments to creditors due at December 31, 2017, plus expenses related to the completion of the CHANGE-MS study. The Company thus expects its cash consumption to decrease significantly from the second half of 2018 onwards.

GeNeuro’s cash and cash equivalents stood at €20.0 million at March 31, 2018, providing a financial runway till mid-2019.

Key clinical and regulatory advances during the quarter

- In late March 2018, GeNeuro published the results of its Phase IIb clinical trial of GNbAC1 at 12 months in multiple sclerosis. For the first time, a therapy has successfully demonstrated a major impact in a large-scale clinical trial (270 patients) on three key neuroprotection markers known to be linked to disease progression, without affecting the patients’ immune system. The results were achieved solely by neutralizing a pathogenic protein produced by patients, called pHERV-W Env, demonstrating its causal role in neurodegeneration. GeNeuro and Servier are evaluating the next steps to this success in the clinical development of GNbAC1. Multiple possibilities are open to them in the various forms of multiple sclerosis, both as a monotherapy for patients with progressive forms of the disease, and in combination with existing drugs for its remitting forms.

1 Under IAS 18, milestone payments received are recognized in revenues on the income statement as and when the relevant services are provided in respect of the Phase IIb clinical trial, which was conducted by and under the authority of GeNeuro. They have thus been staggered over the full duration of the clinical trial, that is between 2015 and 2018.
In February 2018, GNbAC1 received Orphan Drug Designation (ODD) from the US Food and Drug Administration (FDA) in the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP), a rare autoimmune neurological disorder of the peripheral nervous system. It has been observed previously that the pHERV-W Env protein, which is targeted by GNbAC1, was present in approximately half of CIDP patients. This protein impairs the integrity of Schwann cells, which maintain the myelin sheath around peripheral nerves, through the induction of the IL6 and CXCL10 cytokines that locally recruit inflammatory cells and inhibit remyelination. In the United States, the prevalence rate of CIDP is estimated to be 9 cases per 100,000 people. Current long-term therapy is often limited by side effects, and one-third of patients are refractory to existing treatments.

During the quarter, GeNeuro also continued its developments in type 1 diabetes and amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig’s disease. In type 1 diabetes, the preliminary results are expected in the third quarter of 2018 for the phase IIa trial for which 60 patients were enrolled on schedule in January 2018. In ALS, the Cooperative Research and Development Agreement with the US National Institutes of Health remains in force, with preclinical results anticipated during the second half of 2018.

Next financial report:
Second-quarter 2018 revenues and cash position: Thursday July 26, 2018 (after market closes)

Forthcoming investor and industry events:

European Mid Cap Event
May 16, 2018, Copenhagen, Denmark

Ordinary general meeting of the shareholders
May 24, 2018, Geneva, Switzerland

Gilbert Dupont Société de Bourse - Healthcare Forum
May 29, 2018, Paris, France

BIO International Convention 2018
June 5-7, 2018, Boston, United States

Kepler Biotech Days
June 20, 2018, Paris, France

Annual Meeting of the American Diabetes Association
June 22-26, 2018, Orlando, United States

Spring Mid Cap Event
June 27-28, 2018, Paris, France

About GeNeuro

GeNeuro’s mission is to develop safe and effective treatments against neurological disorders and autoimmune diseases, such as multiple sclerosis and Type 1 Diabetes, 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 29 employees and rights to 16 patent families protecting its technology.

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