GeNeuro Reports 2016 Half-Year Results and Provides Corporate Update

- Successfully completed IPO raising €33 million on EURONEXT Paris
- Robust cash position of €42.4 million
- GeNeuro is executing its business strategy on track as presented in its IPO
  - GNbAC1 CHANGE-MS Phase 2b on track to report in Q4 2017
  - Over half of 260 patients enrolled in CHANGE-MS study
  - Strengthened regulatory and clinical development team
  - Planning of new clinical trials on MS in the US and in other indications

Geneva, Switzerland, 29 September 2016 – GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for autoimmune diseases including multiple sclerosis (MS), today reported its half-year financial results for the period ending June 30, 2016 and provided a corporate update.

“Our EURONEXT Paris IPO in April provided us with €33 million in additional funding to deliver on the development of what we believe is the most promising new potential treatment for MS, GNbAC1, a therapeutic candidate that could address not only the symptoms but also the cause of the disease,” stated Jesús Martin-Garcia, Chief Executive Officer at GeNeuro. “The development of GNbAC1 is progressing ahead of schedule and we are planning to initiate additional trials in MS in the US as well as in other indications.”

Product Development Highlights

January – June 2016

GeNeuro’s most advanced therapeutic candidate, GNbAC1, is a humanized monoclonal antibody that neutralizes a protein called MSRV-Env, encoded by human endogenous retroviruses (HERV) which constitute 8% of the human DNA. GeNeuro is conducting a European Phase 2b study, CHANGE-MS, in patients with relapsing remitting multiple sclerosis (RRMS), which has now passed the halfway mark in recruitment, ahead of schedule. The 6-month initial results of this study will be available in Q4 2017. GeNeuro believes that these results will establish the role of MSRV-ENV as a causal factor of MS and provide patients with a new and powerful therapeutic.

GeNeuro has also reinforced its clinical and regulatory teams by hiring four new professionals to execute on the initiation of trials for its lead candidate GNbAC1 in the US for MS and in new indications.

Outlook

Initiation of GNbAC1 trials in the US: a new focus on Secondary Progressive patients

The initiation of clinical trials for GNbAC1 in the US is a strategic priority for GeNeuro to prepare a rapid transition between the ongoing Phase 2b study and the global Phase 3 study that will be funded by Servier. The faster than expected recruitment in the European Phase 2b study in RRMS patients makes it difficult to add centers for this trial in the US without slowing the CHANGE-MS trial. Therefore, GeNeuro is planning instead to capitalize on the work it has done to prepare for clinical trials in US by initiating a separate and complementary Phase 2 study in secondary progressive MS patients, a patient population distinct from
RRMS patients. This study will examine the effect of different repeated doses of GNbAC1 on safety and on biomarkers of microglial activation, remyelination and neuroprotection.

GeNeuro plans to submit an IND for this new Phase 2 trial in the coming weeks, with the objective of starting the study early next year. Results would be expected to be concomitant to the full Phase 2b RRMS study results, i.e. by mid-2018.

*Launching clinical trials in other indications for GNbAC1*

GeNeuro has focused its research on the HERV protein MSRV-Env and has established relationships with third-party research groups studying this protein and other HERV proteins in different diseases.

GeNeuro and third-party research groups have substantiated the presence of the toxic MSRV-Env protein in other organs affected by poorly understood diseases, such as in the pancreases of Type 1 diabetes (T1D) patients and in the peripheral nerves in chronic inflammatory demyelinating polyneuropathy (CIDP), an orphan neurological disease also called “peripheral MS”.

GeNeuro is preparing a Phase 2a proof-of-concept trial focusing on T1D patients positive for MSRV-ENV, which will start in early 2017.

In April 2016, GeNeuro published the paper “Human Endogenous Retrovirus and Neuroinflammation in Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)” in EBioMedicine, showing that a biomarker-driven therapeutic strategy targeting MSRV-Env with a neutralizing antibody such as GNbAC1 may offer new perspectives for treating CIDP patients with MSRV-Env expression. A proof-of-concept Phase 2a is being prepared, for the second half of next year.

**Key Financials**

“The financial results for the first half of 2016 are in line with our expectations. Mainly driven by the rapid recruitment of our Phase 2b study, our total operating expenses have increased significantly, to €10.5 million vs €2.3 million in the same period of last year. Out of this year’s amount, €3.8 million are one-time costs, including €1.8 million of IPO costs,” said Miguel Payró, Chief Financial Officer at GeNeuro. “As already mentioned, our agreement with Servier fully covers the costs of our on-going European Phase 2b study and also commits Servier to funding a global Phase 3 subject to the exercise of their licensing option.”

On September 27, 2016, the Board of Directors of GeNeuro reviewed and approved the financial statements for the six-month period ended June 30, 2016. The Statutory Auditors have conducted a review of the interim consolidated financial statements. The half-year financial report in French and English is available in the Investors section on [www.geneuro.com](http://www.geneuro.com).
Operating revenues amounted to €3,434 during 1H2016 vs. €526 for the same period of last year. This corresponds to revenue recognized by GeNeuro with respect to milestone payments already received from Servier as part of the ongoing CHANGE-MS clinical trial for GNbAC1. The increase in income during the first half of 2016 is due to the launch of the phase 2b clinical trial at the end of 2015 (for more explanations, please refer to note 8 of the notes to the Company’s consolidated half-yearly accounts).

Research & Development expenses increased significantly compared to the first half of 2015, growing from €1,802 to €7,298 due to the launch of the phase 2b clinical trial at the end of 2015 and its rapid recruitment. This resulted in 1H2016 costs for studies and research of €4,870 vs. €648 in the same period of 2015; the 1H2016 amount includes €1,057 of production costs for GNbAC1, which will cover the needs of our existing and planned Phase 2 studies in MS and other indications. R&D personnel expenses also increased from €778 in 1H2015 to €1,245 due to the strengthening of GeNeuro’s clinical and regulatory teams. Finally, licensing costs rose from €24 in 1H2015 to €907 in 1H2016 as a result of a milestone payment of CHF 1 million (€907) to bioMérieux resulting from the start of the Phase 2b study; the next milestone payment is due upon entry into a Phase 3 study. In total, one-time R&D costs for production and licensing amount to €1,964 in 1H2016.

General and administrative expenses increased markedly to €3,217 in 1H2016 from €546 during the same period of 2015. Of this amount, €1,764 corresponds to charges related to the Company’s IPO on Euronext Paris. Administrative personnel expenses increased to €779 from €267 as a result of the strengthening of the Company’s management team required for its development. A charge of €273 was also recorded during 1H 2016 for share-based payments; no similar charge had been recorded during the first half of 2015.

The Company recorded a net loss of €6,815, in-line with management’s expectations.

Cash and cash equivalents at 30 June 2016 amounted to €42,408 vs. €19,560 at 31 December 2015. The increase is due primarily to the Company’s IPO, which generated €31,376 in net proceeds, mitigated mostly by cash used in operations (€7,749) and cash used by the share liquidity contract with Gilbert Dupont (€750).
Capital increase. In the first half of 2016, GeNeuro successfully completed its IPO, raising €33 million on EURONEXT Paris on April 19. GeNeuro (ISIN code CH0308403085; ticker GNRO) was listed through the admission to trading of 14,658,118 shares, including 2,538,500 new shares issued under a Global Offering, made up of a Public Offering that included an Open Price Public Offering and a Global Placement with institutional investors in France and other countries. As indicated at launch of the Offering, the IPO was supported by leading French life science groups, Institut Mérieux and Servier, which subscribed shares for a total amount of €9.3 million. Approximately 78% of the funds raised among the new shareholders have been subscribed by international investors, particularly from the United Kingdom and in the United States.

Business Outlook

GeNeuro is executing its business strategy on track as presented in its IPO. Specifically, GeNeuro expects full recruitment of CHANGE-MS in Q1 2017 on or ahead of schedule and to announce results in Q4 2017 as planned.

GeNeuro projects cash utilization (excluding IPO-related costs) to be roughly €17 million for 2016, of which approximately €7 million in the second half of 2016. This forecast includes:

- continued progress of GNbAC1 in the CHANGE-MS Phase 2b
- planning for U.S. clinical study of GNbAC1 in secondary progressive MS patients
- planning for clinical studies in Type 1 diabetes and CIDP.

“The Servier milestone payments and the proceeds from the IPO cover our ongoing and planned Phase 2 studies in MS, including in the US, as well as in other indications, which puts GeNeuro in a very favourable financial situation,” concluded Jesús Martin-Garcia.

About GNbAC1

The development of GNbAC1 is the result of 25 years of research into human endogenous retroviruses (HERVs), including 15 years at Institut Mérieux and INSERM, a French national medical research institute. Found in the human genome, certain HERVs have been linked to various autoimmune diseases. Specifically, MSRV-ENV, which is found on the active lesions of MS patients, has been shown to have both a pro-inflammatory action via interaction with the TLR4 receptor of innate immunity, as well as to stop the differentiation of oligodendrocyte precursor cells, which are responsible for remyelinating brain lesions. By neutralizing MSRV-ENV, GNbAC1 could block a key factor promoting the inflammation on the plaques, as well as allowing the remyelination repair process to restart. As MSRV-ENV has no known physiological function, GNbAC1 is expected to have a good safety profile, without affecting the patient’s immune system, as observed in all clinical trials to date.

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; a new frontier pioneered by GeNeuro since 2006 and based on research by Institut Mérieux and INSERM.

GeNeuro is based in Geneva, Switzerland and has R&D facilities in France at sites in Archamps, Haute-Savoie and Lyon. It has 25 employees and rights to 16 patent families protecting its technology.

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