

GeNeuro: Cash position at December 31, 2019, Business Update and Outlook for 2020

- Cash position of €5.9 million at December 31, 2019
- New clinical trial of temelimab in multiple sclerosis (MS) with Karolinska Institutet / Academic Specialist Center of Stockholm to start in Q1 2020
- Full ANGEL-MS results showing neuroprotective effects of temelimab at 24 months presented at ECTRIMS 2019 congress
- Constructive partnering discussions for temelimab ongoing, supported by strong results from ANGEL-MS clinical trial
- Broadening pipeline through ongoing preclinical development of a new antibody against Amyotrophic Lateral Sclerosis, aiming to start clinical studies in 2021

Geneva, Switzerland, January 30, 2020 – 6:00pm CET – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments focused on stopping causal factors driving the progression of neurodegenerative and autoimmune diseases, today announced its cash position at December 31, 2019, issued a business update and provided an outlook on its 2020 activities.

*“GeNeuro continued to make significant clinical progress in 2019,” said **Jesús Martin-Garcia, CEO of GeNeuro**. “The full 2-year results of our ANGEL-MS clinical trial of temelimab in multiple sclerosis, which were presented in September at the ECTRIMS 2019 congress, have confirmed the neuroprotective effect of temelimab in MS and demonstrated its potential against progression of the disease. Building on this, we announced in November 2019 a collaboration for a new clinical trial of temelimab in MS with clinical researchers of the Karolinska Institutet and the Academic Specialist Center (ASC), Stockholm, Sweden, led by Dr. Fredrik Piehl, Professor of Neurology at the Department of Clinical Neurosciences of the Karolinska Institutet, and head of research at the MS clinic at ASC.”*

The trial will be conducted at the Center for Neurology of ASC, the largest MS center in Sweden, which treats approximately 2,400 patients. The one-year trial will enroll initially 40 patients whose disability progresses without relapses and will document the safety and tolerability of temelimab following higher doses, as well as efficacy based on the latest biomarkers associated with disease progression. The study aims to start enrolling patients in Q1 2020.

*“We also continue to hold constructive discussions about the next steps in the development of temelimab. Furthermore, we now anticipate that our antibody program in ALS could enter the clinic in 2021. Our cash balance at year-end 2019 covers our needs into Q4 2020 and we will shortly launch a capital increase to secure additional resources to extend our runway,” added **Mr. Martin-Garcia**.*

Cash position at December 31, 2019

At December 31, 2019, GeNeuro had €5.9 million in cash and cash equivalents. Based on its planned activities and operations, the Company estimates that its financial resources are sufficient to cover its upcoming deadlines, operational expenses and investments into Q4 2020 (including costs up to that point in time related to the remaining ongoing pre-clinical programs and to the planned launch of the single-center MS trial with the Karolinska Institutet / ASC), assuming that the shareholder loan from GNEH, a subsidiary of Institut Mérieux, would be either converted or extended beyond September 30, 2020.

Continuing the trend observed during the 2019 financial year, the cash consumption related to GeNeuro's operating and investing activities was reduced to €2 million in Q4 2019.

Development of temelimab in Multiple Sclerosis (“MS”)

In March 2019, GeNeuro published the top-line 96-week results of its extension Phase 2b clinical trial, ANGEL-MS, which showed that the 18mg/kg dose of temelimab (GNbAC1) had remarkably consistent benefits over all other groups on key MRI measures linked to MS disease progression, thereby confirming and extending the results of CHANGE-MS at Week 48.

The data showed that, after two years of treatment, patients originally randomized to temelimab at 18 mg/kg showed evidence for continued relative improvements in MRI-based neurodegenerative outcomes, such as brain volumes, magnetization transfer ratio (MTR) and black holes during ANGEL-MS up to 96 weeks compared to all other groups. Importantly, these effects were not driven by an anti-inflammatory effect. These data were presented at ECTRIMS 2019 in Stockholm, Sweden: <http://www.geneuro.com/data/news/GeNeuro-ECTRIMS-PR-160919-ENG.pdf>

By targeting fundamental underlying mechanisms of neurodegeneration in MS, such as neutralizing microglial-mediated damage, as well as restoring OPC (Oligodendrocyte Precursor Cells) remyelination capacity, temelimab may address the critical unmet medical need of blocking disability progression independent of relapses in MS. As the ANGEL-MS study showed, temelimab continued to be safe and well tolerated over this extended treatment period, which allows to consider new therapeutic solutions, with the objective to bring new benefits against disease progression across all forms of MS. GeNeuro is now focusing on neurodegeneration and disease progression, with temelimab either as a monotherapy for “non-active” progressive patients, and/or as an adjunctive therapy for remitting patients in combination with existing immunomodulatory drugs addressing neuroinflammation. The Company continues to actively pursue partnership discussions for the MS indication at the same time as it is working on the design of potential future clinical trials in the progressive forms of MS.

In November 2019, GeNeuro announced a collaboration for a new clinical trial of temelimab in MS with clinical researchers of Karolinska Institutet and the Academic Specialist Center (ASC), Stockholm, Sweden. GeNeuro expects to initiate in Q1 2020 this one-year, single center Phase 2 clinical trial with higher doses of temelimab in MS conducted by the Academic Specialist Center (Karolinska Institutet) of Stockholm. The study will initially enroll 40 patients whose disability progresses without relapses. It will assess safety, tolerability and efficacy based on the latest biomarkers associated with disease progression. Results are expected to be announced in H2 2021.

Amyotrophic Lateral Sclerosis (“ALS”)

Beyond multiple sclerosis, GeNeuro is also leveraging the large potential of its HERVs platform, notably through providing new therapeutic options for patients affected with severe neurodegenerative disease. GeNeuro signed an agreement in 2017 with NINDS (National Institute of Neurological Disorders and Stroke, part of the U.S. National Institutes of Health), to develop novel therapeutic antibodies for the treatment of ALS. GeNeuro has initiated a preclinical development program for its pHERV-K Env antibody in this indication and aims to reach an IND (Investigational New Drug) in 2021. Accordingly, GeNeuro now believes that this drug candidate could enter the clinic in 2021.

Type 1 Diabetes (“T1D”)

In May 2019, GeNeuro announced the results from the 6-month extension of a temelimab Phase 2a in T1D, which confirmed all previously-observed positive observations, meeting its primary objective on safety and benefit on the number of hypoglycemic events. GeNeuro believes these data open the door to further development in early-onset T1D pediatric patient population but, based on its current situation, has decided to temporarily sideline the development of temelimab in T1D.

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 23 employees and rights to 17 patent families protecting its technology.

For more information, visit: www.geneuro.com

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