

Press release

# GeNeuro Reports 2018 Full-Year Results and Provides Corporate Update

- Solid cash position of €16.5 million, including credit facility of €7.5 million
- Successful ANGEL-MS Phase 2b extension study results confirm and extend the neuroprotective effects of temelimab in MS
- Final 12-month results from Phase 2a Type 1 Diabetes trial expected Q2 2019

**Geneva, Switzerland, April 1, 2019 – 7:30am CEST –** GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for autoimmune diseases, including multiple sclerosis (MS) and Type-1 Diabetes (T1D), today reported its full-year results for the year ended December 31, 2018 and provided a corporate update.

The completion of the temelimab Phase 2b study in MS has led to a reduced cash burn during 2018, as expected, and this will further decrease in 2019. GeNeuro's cash position at year-end 2018, coupled with the €7.5 million credit facility granted by GNEH SAS, an Institut Mérieux subsidiary, on which the company received a first draw-down of €2.5 million at the end of March 2019, provide solid financial visibility until mid-2020 in terms of financing all our current activities.

"GeNeuro is making significant clinical progress in 2019 and has a solid financial visibility until mid-2020. We continue our constructive partnership discussions about the next steps in the development of our lead product temelimab and anticipate that our antibody program in ALS could enter the clinic by mid-2020," said **Jesús Martin-Garcia, CEO of GeNeuro**.

"We are extremely pleased with the data, communicated in March 2019, from the ANGEL-MS Phase 2b extension study in multiple sclerosis, which clearly confirm and extend the robust and consistent effects of temelimab on key MRI markers of neuroprotection, and we are excited by the early signs of clinical benefit. The fact that these results appear to be independent of inflammatory activity opens a novel therapeutic perspective against disease progression in multiple sclerosis," **Mr Martin-Garcia added.** "This further reinforces our determination to continue the development of temelimab in patients with non-active, progressive MS. By targeting potential causes of neurodegenerative diseases, we hope to open a new, safe and effective therapeutic pathway for patients."

## PRODUCT DEVELOPMENT HIGHLIGHTS SINCE JANUARY 1, 2018

## Multiple Sclerosis

Temelimab (GNbAC1), GeNeuro's most advanced therapeutic candidate, is a humanized monoclonal antibody that neutralizes pHERV-W env, a pathogenic protein that has been identified in brain lesions of patients with MS, particularly in active lesions, and appears to activate microglia and impair oligodendrocyte-mediated remyelination in the brain.

GeNeuro has now successfully completed both the CHANGE-MS European Phase 2b trial in patients with remitting relapsing multiple sclerosis (RRMS) and its ANGEL-MS extension study. Across the two studies, a total of 154 patients received temelimab for 96 weeks or more, with approximately 90% of patients having received at least 86 weeks of treatment. For patients not having completed 96 weeks, the end-of-study visit results were used in the analyses, with last observation carried forward. The final ANGEL-MS 48-week results were communicated on March 12, 2019 and showed that the 18mg/kg dose of temelimab continued to have remarkably consistent benefits over all other groups on key MRI measures linked to MS disease progression, confirming and extending the results of CHANGE-MS at Week 48. The 18mg/kg treatment arm also showed lower probability for 12-week confirmed disability progression (Survival Wilcoxon test p=0.34), whilst the

measure of 25-foot timed-walk also showed remarkable stability for the 18mg/kg cohort, with only 2.4% of patients worsening more than 20% over two years (dose effect p=0.03). While these clinical measures are very encouraging, the limited size and relapsing nature of the cohort for clinical progression measures does not allow for definitive conclusions. At the same time, temelimab continued to show an excellent safety and tolerability profile throughout. As a result, temelimab offers promise to treat non-active progressive patients and could have potential synergies with existing anti-inflammatory drugs in relapsing MS patients.

On January 21, 2019, GeNeuro published the results of a high-dose Phase 1 clinical trial for temelimab, which support and expand the large amount of positive clinical data GeNeuro has compiled regarding temelimab's safety and tolerability. The success of this Phase 1 study allows GeNeuro to explore whether higher doses of temelimab could provide additional benefit to MS patients, at the same time as it broadens the possible therapeutic modalities for this drug candidate.

#### Type 1 Diabetes

In parallel with these developments in MS, GeNeuro is conducting a Phase 2a clinical trial of temelimab in 60 recently diagnosed adults with type I diabetes (T1D). At a 6-month interim analysis, the study met its primary end-point of safety in this new patient population, as well as several pharmacodynamic markers of activity. The pathogenic envelope protein, pHERV-W Env, which is neutralized by temelimab has been detected post-mortem in the pancreas in about two thirds of patients with T1D.

#### Amyotrophic Lateral Disease (ALS)

Following positive data from its collaboration with the NINDS, part of the US National Institutes of Health (NIH), in preclinical amyotrophic lateral sclerosis (ALS) models, GeNeuro signed an exclusive global license with NINDS covering a program to develop antibodies that block the activity of pHERV-K Env (a pathogenic envelope protein of the HERV-K family of human endogenous retroviruses), a potential key factor in the development of ALS. GeNeuro is advancing a preclinical ALS development program, aiming to obtain an IND by mid-2020.

## **KEY FINANCIALS 2018**

The Board of Directors of GeNeuro reviewed and approved the financial statements for the twelve-month period ended December 31, 2018. The Statutory Auditors have conducted a review of the annual consolidated financial statements.

	31/12/2018	31/12/2017
GENEURO Consolidated Income Statement (in thousands of EUR)	12 months <i>Audited</i>	12 months <i>audited</i>
Income	7,463.1	14,948.8
Research and development expenses		
Research and development expenses	(12,847.8	(17,523.2)
Subsidies	1,917.9	1,361.8
General and administrative expenses	(4,685.8)	(4,596.5)
Other Income	64.0	69.2
Operating loss	(8,088.6)	(5,739.9)
Net loss for the period	(8,327.8)	(5,837.2)
	31/12/2018	31/12/2017
Basic losses per share (EUR/share)	(0.57)	(0.40)
Diluted losses per share (EUR/share)	(0.57)	(0.40)

**Income** amounted to  $\notin$ 7.5 million in 2018, compared to  $\notin$ 14.9 million in 2017. This decrease is due to the completion of the CHANGE-MS Phase 2b clinical trial of temelimab during the first half of 2018 and the accounting recognition during that period of the entire balance of the  $\notin$ 29.5 million milestone payments paid to GeNeuro by Servier as part of the cooperation agreement. No further income will be recognized in the absence of a new partnership agreement.

**Research & Development** expenses decreased by  $\leq 4.7$  million, or 27%, in 2018 compared to 2017, mainly due to a  $\leq 2.6$  million decrease in clinical trial costs (reflecting primarily the completion of the CHANGE-MS Phase 2b in MS) and to a  $\leq 0.6$  million decrease in R&D payroll expense, resulting from lower personnel levels after the end of the CHANGE-MS study. Subsidies, under the form of research tax credits linked to R&D activities, increased by  $\leq 0.6$  million. As a result, net R&D expenses decreased by  $\leq 5.2$  million in 2018 compared to 2017.

**General and administrative** expenses increased by €0.1 million in 2018, compared to an increase of €0.9 million in 2017. Payroll expenses increased by €0.1 million compared to 2017.

**Cash and cash equivalents** amounted to €9.0 million at December 31, 2018, compared to €26.6 million at December 31, 2017. This decrease is due to continued clinical development of temelimab. 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 €17.5 million in 2018 compared to €7.6 million for 2017. However, after excluding the favorable impact in 2017 of Servier's advances designed to finance the ANGEL-MS study and the €12.0 million milestone payment received from Servier in December 2017, adjusted cash consumption for 2017 was €23.1 million compared to €17.5 million in 2018; this €5.6 million decrease is consistent with the reduced activity of clinical trials during 2018 and is also in line with the Company's expectations. Taking into account the €7.5 million credit facility granted by its shareholder GNEH SAS, a subsidiary of Institut Mérieux, on which the Company has already received a first drawdown of €2.5 million at the end of March, **the Company's cash position is funded until mid-2020**.

## **Business Outlook**

GeNeuro's priorities for 2019 remain the development of its clinical and scientific research programs:

- Build on the positive CHANGE-MS and ANGEL-MS Phase 2b clinical trial results on key MRI measures of disease progression in MS patients to advance the Company's partnership discussions; these results confirm the potential of temelimab to act against disease progression not associated with inflammatory activity, the largest unmet medical need in this indication;
- Continue clinical development of temelimab in other indications: full 12-month results from the Phase 2a study in Type 1 Diabetes are expected in Q2 2019;
- **Continue the pre-clinical** program in Amyotrophic Lateral Sclerosis (ALS, in partnership with the US National Institutes of Health), with the objective to obtain an IND by mid-2020.

## 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 27 employees and rights to 17 patent families protecting its technology.

For more information, visit: <u>www.geneuro.com</u>

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