

## GeNeuro Reports 2019 Full-Year Results and Provides Corporate Update

- Strong financial visibility, with cash position of €15 million pro forma, including net proceeds from January 2020 capital increase
- Company's operations funded until mid-2022
- New clinical trial of temelimab in multiple sclerosis (MS) with Karolinska Institutet / Academic Specialist Center of Stockholm, starting as soon as COVID-19 context allows
- Broadening pipeline with preclinical development of new antibody against Amyotrophic Lateral Sclerosis; aiming to start clinical studies in 2021
- Enrichment of the shareholder base with new leading international specialist investors alongside Institut Mérieux and Ecllosion2

**Geneva, Switzerland, April 7, 2020 – 7:30am CEST** – 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 reported its full-year results for the year ended December 31, 2019 and provided a corporate update.

The completion of the temelimab Phase 2 studies in multiple sclerosis and Type 1 diabetes has led to a substantially reduced cash burn in 2019, which will further decrease in 2020. GeNeuro's cash position at year-end 2019, including the €17.5 million proceeds from the capital increase completed on January 31, 2020, provides solid financial visibility until mid-2022 based on currently planned 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 demonstrated the continued effect on all key MRI markers associated with the progression of the disease, making it a highly attractive candidate to address this key unmet medical need. Building on this, we initiated a collaboration for a new clinical trial of temelimab in MS with the Karolinska Institutet and the Academic Specialist Center (ASC), Stockholm, Sweden."*

*"In the current COVID-19 context however, we have decided, together with our collaboration partners, to postpone temporarily this trial to reduce the demands on healthcare professionals, prioritize treatment of COVID-19 patients and safeguard the wellbeing of MS patients," Mr Martin-Garcia added. "We must put the fight against COVID-19 and the safety of MS patients first. We are working to ensure that there will be a smooth, ethical and efficient transition, such that we can initiate the trial as soon as possible."*

*"The €17.5 million capital increase we completed in January 2020 provides GeNeuro with operating capital to mid-2022 and the means to complete the planned one-year Karolinska study of higher doses of temelimab in MS patients. GeNeuro has also enriched its shareholder base as Institut Mérieux and Ecllosion2, who have supported the Company for over a decade, have been joined by other leading international specialist investors, including Invesco, Invus, and Van Herk Investments, providing cash for operations until mid-2022," stated Miguel Payró, Chief Financial Officer at GeNeuro.*

## PRODUCT DEVELOPMENT HIGHLIGHTS SINCE JANUARY 1, 2019

### Multiple Sclerosis

In March 2019, GeNeuro published the top-line 96-week results of its extension Phase 2b clinical trial, ANGEL-MS, which demonstrated 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, the patients originally randomized to 18 mg/kg temelimab showed evidence of continued 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 the fundamental underlying mechanisms of neurodegeneration in MS, i.e. neutralizing microglial-mediated damage, as well as restoring OPC<sup>1</sup> remyelination capacity, temelimab may address the critical unmet medical need of blocking disability progression independent of relapses in MS.

As the study demonstrated, temelimab continued to be safe and well tolerated over this extended treatment period, which allows new therapeutic solutions in combination with anti-inflammatory drugs or as a monotherapy to be considered, with the objective to bring new benefits against disease progression across all forms of MS.

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 the disease.

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, 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.

GeNeuro expects to launch, as soon as the COVID-19 situation permits, a one-year single center Phase II clinical trial with higher doses of temelimab in MS conducted by the ASC, initially in 40 patients whose disability progresses without relapses. This study will assess safety, tolerability and efficacy measures based on the latest biomarkers associated with disease progression. Results are expected to be announced in the second half of 2021.

### Amyotrophic Lateral Disease (ALS)

GeNeuro also seeks to leverage the potential of targeting human endogenous retroviruses (HERVs) through providing new therapeutic options for patients affected with severe neurodegenerative disease. GeNeuro signed an agreement in 2017 with National Institute of Neurological Disorders and Stroke (NINDS), 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 obtain an IND (Investigational New Drug) from the FDA by 2021. Accordingly, GeNeuro now believes that this product could enter the clinical stage of development in 2021.

### Type 1 Diabetes (T1D)

In May 2019, the Company announced the results from the six-month extension of its Phase 2a study of temelimab in T1D, which confirmed all previously observed positive observations during the trial, meeting its primary objective.

GeNeuro believes these data open the door to further development in early-onset T1D pediatric patient population but, based on its current strategy, has decided to temporarily pause development of temelimab in T1D in order to prioritize the development for MS.

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<sup>1</sup> Oligodendrocyte precursor cell

## KEY FINANCIALS 2019

The Board of Directors of GeNeuro reviewed and approved the financial statements for the year ended December 31, 2019. The Statutory Auditors have conducted a review of the annual consolidated financial statements.

GeNeuro Consolidated Income Statement (in thousands of EUR)	31/12/2019 12 months Audited	31/12/2018 12 months Audited
Income	-	7,463.1
Research and development expenses		
Research and development expenses	(6,174.7)	(12,847.8)
Subsidies	912.4	1,917.9
General and administrative expenses	(3,744.1)	(4,685.8)
Other Income	16.2	64.0
<b>Operating loss</b>	<b>(8,990.2)</b>	<b>(8,088.6)</b>
<b>Net loss for the period</b>	<b>(9,460.8)</b>	<b>(8,327.8)</b>
	<b>31/12/2019</b>	<b>31/12/2018</b>
<b>Basic losses per share (EUR/share)</b>	<b>(0.65)</b>	<b>(0.57)</b>
<b>Diluted losses per share (EUR/share)</b>	<b>(0.65)</b>	<b>(0.57)</b>

**Income** of €7.5 million in 2018 related to the accounting recognition of the balance of the €29.5 million milestone payments paid by Servier to GeNeuro as part of the former cooperation agreement signed in 2014. As indicated in 2019, no further income was recognized in 2019 in the absence of a new partnership agreement.

**Research & Development** expenses decreased by €6.7 million, or 52%, in 2019 compared to 2018, mainly due to the completion of the Company's clinical trials (with a €6.0 million decrease in clinical trial costs) and to a €0.9 million decrease in R&D payroll expense, resulting from lower personnel levels after the end of the trials. Subsidies, under the form of research tax credits linked to R&D activities, decreased by €1.0 million in 2019 over 2018. As a result, net R&D expenses decreased by €5.6 million in 2019 compared to 2018.

**General and administrative** expenses decreased by €0.9 million in 2019, compared to an increase of €0.1 million in 2018, highlighting GeNeuro engagement to prioritize resources behind Research & Development.

**Cash and cash equivalents** amounted to €15.0 million on a pro forma basis at December 31, 2019, taking into account the net proceeds of the January 2020 capital increase, compared to €9.0 million at December 31, 2018. Reported cash and cash equivalent at December 31, 2019 was €5.9 million. The decrease on the reported, rather than pro forma, basis is due to the 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 €9.9 million in 2019, compared to €17.5 million in 2018; this €7.6 million decrease is consistent with the reduced activity of clinical trials during 2019 and is also in line with the Company's expectations. Taking into account the €9.1 million net proceeds from the January 2020 capital increase, **the Company's operations are funded until mid-2022.**

## BUSINESS OUTLOOK

GeNeuro's priorities for 2020 remain the development of its clinical and scientific research programs:

- **Advance the Karolinska trial** once the COVID-19 situation has improved to the point where clinical trials in MS may be resumed, seeking to complete recruitment during 2020;
- **Continue partnership discussions on the basis of the positive CHANGE-MS and ANGEL-MS Phase 2b clinical trial** results on key MRI measures of disease progression in MS patients. These results confirm the differentiated clinical profile of temelimab and its potential to act against disease progression not associated with inflammatory activity, the largest unmet medical need in this indication;
- **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 2021;

- **Clinical development in other indications** will only take place subject to securing specific non-dilutive funding.

## **COVID-19 PANDEMIC SITUATION: IMPLEMENTATION OF A BUSINESS CONTINUITY PLAN AND OF ADAPTED MANAGEMENT MEASURES**

In the current context, the Company wishes to state its strict adherence to the recommendations issued by the World Health Organization and by local governments in terms of health & hygiene and organizational standards, in order to ensure the health and safety of its staff and their families.

Accordingly, GeNeuro has successfully implemented home office processes whenever possible for the majority of its employees. As previously stated, the Company has shown its commitment to patients and clinical trial centers by encouraging the allocation of clinical resources towards COVID-19 affected patients, so as to protect these patients at the same time as ensuring the safety of fragile patients suffering from neurodegenerative diseases. GeNeuro thus reaffirms its solidarity with all healthcare personnel and its safety policies for patients involved in its clinical trials.

Finally, although the Company currently benefits from a strong financial visibility, it reiterates its rigorous cash management, which will be maintained and strengthened in order to adapt to the current circumstances.

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

For more information, visit: [www.geneuro.com](http://www.geneuro.com)

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