*Press release*

# GeNeuro announces the publication in *Multiple Sclerosis* of results from CHANGE-MS and ANGEL-MS studies

- Data showed promising anti-neurodegenerative effect and supports continued development of temelimab against disability progression in MS
- CHANGE-MS and ANGEL-MS were Phase 2, double-blind 48-week trial + 48-week extension in relapsing-remitting MS, assessing safety and efficacy of temelimab
- Ongoing Phase 2 study at Karolinska Institutet/Academic Specialist Center of Stockholm, Sweden, with results expected Q1 2022

**Geneva, Switzerland, July 15, 2021 – 08:00am CEST –** GeNeuro (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical developing new treatments for neurodegenerative diseases, such as multiple sclerosis (MS), today announced publication in *Multiple Sclerosis* of the safety and efficacy results from its temelimab CHANGE-MS and ANGEL-MS clinical studies.

These studies were a Phase 2, double-blind, 48-week trial (CHANGE-MS) in relapsing-remitting multiple sclerosis (RRMS), followed by a 48-week extension phase (ANGEL-MS). The studies assessed the safety and efficacy of temelimab on MRI markers of inflammation and neurodegeneration. A total of 270 patients were randomized to receive monthly intravenous temelimab (6, 12, or 18 mg/kg) or placebo for 24 weeks; at week 24, placebo-treated participants were re-randomized to treatment groups. A total of 92% of patients with RRMS who completed the CHANGE-MS study opted to continue the study and were included in the ANGEL-MS extension phase. While the primary endpoint on acute inflammation was not met, as announced in August 2017, temelimab already showed promising signs on MRI markers of neurodegeneration at 48 weeks (CHANGE-MS, top-line announced in March 2018), which were sustained or enlarged over the 48-week extension (ANGEL-MS, top-line announced March 2019). No safety issues emerged.

These results put temelimab in a unique position against neurodegeneration in MS, aiming to serve the majority of patients whose disability continues to progress despite being treated with effective therapies against relapses. Temelimab's specific mode of action, in neutralizing pathogenic HERV-W ENV, and its excellent tolerability could open the door to new combination approaches to address both relapses and neurodegeneration in MS.

*"Publication of the results from the CHANGE-MS Phase 2 study and its 48-week ANGEL-MS extension confirms the potential of temelimab in MS through a new mechanism of action targeting specifically neurodegeneration. This was a first-in-class ambitious exploratory Phase 2, and its promising results show the importance of pursuing novel paths to achieve progress against the remaining medical need of tackling disability progression in MS,"* said **Prof. Hans-Peter Hartung, Professor of Neurology, Heinrich Heine University Düsseldorf, and principal investigator of the CHANGE-MS and ANGEL-MS studies**.

*"Modern MS therapies are very effective at reducing relapse activity but have little effect on the long-term course of disability. CHANGE-MS and ANGEL-MS have demonstrated that temelimab administration is safe and showed evidence of radiological signs of anti-neurodegenerative effects at 18 mg/kg in patients, so it is important to define the optimal dose in preparation for Phase 3. That is why we look forward to the results of our final Phase 2 study at the Karolinska Institutet/Academic Specialist Center of Stockholm, Sweden, with doses up to 54 mg/kg. This study has recruited MS patients whose acute disease activity has been reset by chronic anti-CD20-Ab therapy with rituximab, but who still experience clinical progression,"* **said Prof. David Leppert, Chief Medical Officer of GeNeuro.**

As previously announced, the Phase 2 ProTEct-MS clinical study (ClinicalTrials.gov: NCT04480307) of temelimab conducted at the Karolinska Institutet's Academic Specialist Center is fully recruited and results are expected in Q1 2022.

## 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 rights to 17 patent families protecting its technology. For more information, visit: www.geneuro.com

## Contacts:


| GeNeuro | NewCap (France) | Halsin Partners | LifeSci Advisors |
|---|---|---|---|
| Jesús Martin-Garcia | Louis-Victor Delouvrier / Mathilde Bohin (investors) | Mike Sinclair (media) | Chris Maggos (investors) |
| Chairman and CEO | +33 1 44 71 98 52 | +44 20 7318 2955 | +41 79 367 6254 |
| +41 22 552 48 00 | Nicolas Merigeau (media) | msinclair@halsin.com | chris@lifesciadvisors.com |
| investors@geneuro.com | +33 1 44 71 94 98 | | |
| | geneuro@newcap.eu | | |


## Disclaimer:

This press release contains certain forward - looking statements and estimates concerning GeNeuro's financial condition, operating results, strategy, projects and future performance and the markets in which it operates. Such forward-looking statements and estimates may be identified by words, such as "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions. They incorporate all topics that are not historical facts. Forward looking statements, forecasts and estimates are based on management's current assumptions and assessment of risks, uncertainties and other factors, known and unknown, which were deemed to be reasonable at the time they were made but which may turn out to be incorrect. Events and outcomes are difficult to predict and depend on factors beyond the company's control. Consequently, the actual results, financial condition, performances and/or achievements of GeNeuro or of the industry may turn out to differ materially from the future results, performances or achievements expressed or implied by these statements, forecasts and estimates. Owing to these uncertainties, no representation is made as to the correctness or fairness of these forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates speak only as of the date on which they are made, and GeNeuro undertakes no obligation to update or revise any of them, whether as a result of new information, future events or otherwise, except as required by law.