Press release

GeNeuro's temelimab Phase 2 multiple sclerosis trial cleared to continue following planned Data Safety Monitoring Board Meeting

- DSMB confirms higher doses of temelimab in ProTEct-MS Phase 2 study are well tolerated
- Study conducted at Karolinska Institutet's Academic Specialist Center (ASC) in Stockholm
- Phase 2 top-line results on track to be reported in Q1 2022

Geneva, Switzerland, March 2, 2021 – 7:30am CET – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company focused on stopping causal factors driving the progression of neurodegenerative and autoimmune diseases, such as multiple sclerosis (MS), today announced that the independent Drug Safety Monitoring Board (DSMB) has concluded the Phase 2 trial of temelimab in MS patients should continue as planned without modification. This follows a pre-determined review of the first 8 patients treated with temelimab for 2 months at doses of 18, 36 and 54 mg/kg. The study, called ProTEct-MS, is being conducted at the Karolinska Institutet's Academic Specialist Center (ASC), in Stockholm (Sweden).

Temelimab is a monoclonal antibody designed to neutralize a pathogenic retroviral envelope protein, pHERV-W Env. Positive results with temelimab have already been achieved in two clinical studies, CHANGE-MS and ANGEL-MS, using a dose of 18mg/kg.

"Our previous clinical studies have demonstrated that temelimab administration is safe and demonstrated positive results on markers of disability progression at 18 mg/kg in patients, so it is now important to define the optimal dose in preparation for the planned Phase III study," **said Prof. David Leppert, Chief Medical Officer of GeNeuro.** *"We are delighted to have the tolerability of the higher doses of temelimab confimed as a further step in our path to deliver a treatment against the critical unmet medical need of blocking disability progression in MS."*

Patient enrolment into ProTEct-MS was recently completed with a cohort of 42 patients being treated for 48 weeks with temelimab (18, 36 and 54 mg/kg) vs. placebo. The double-blind placebo-controlled study has been designed to assess safety, tolerability and efficacy measures based on the latest biomarkers associated with disease progression and will have results in 1Q2022. Patients included in the study had confirmed disability progression without relapses following previous treatment with the anti-CD20 drug rituximab, a highly potent and efficacious drug against acute disease activity (relapses and brain lesion formation).

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 human endogenous retroviruses (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

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