



Press release

# GeNeuro and the Karolinska Institutet's Academic Specialist Center (ASC) Present Temelimab Neurodegeneration Prevention Study at MSVirtual2020

 ProTEct-MS study aims to further explore temelimab's tissue protective and antineurodegenerative effects in cohort of patients whose disability is progressing without relapses

Geneva, Switzerland, September 14, 2020, 7:30am CEST – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurodegenerative and autoimmune diseases, such as multiple sclerosis (MS), today announced that a presentation by Professor Fredrik Piehl of the Karolinska Institutet's Academic Specialist Center (ASC) at MSVirtual2020 (8th Joint ACTRIMS-ECTRIMS Meeting) provided the rationale and outline on the Phase 2 ProTEct-MS clinical study of temelimab initiated earlier this year.

Long-term clinical study data has shown that temelimab, GeNeuro's lead compound under clinical development, has a remarkably consistent neuroprotective effect on key MRI measures linked to MS disease progression. As approximately 80% of MS patients are affected by an increase of disability over time despite the availability of highly effective drugs against inflammatory activity and relapses, temelimab may be able to address this critical unmet medical need of blocking disability progression independent of relapse activity.

pHERV-W Env (human endogenous retrovirus W envelope protein) is expressed by myeloid and microglial cells in MS lesion tissue which leads to neuronal damage and inhibition of myelination by oligodendrocyte precursor cells (OPCs), Temelimab is a monoclonal antibody designed to neutralize pHERV-W Env and hence may exert a direct neuroprotective effect.

As part of the <a href="ProTEct-MS">ProTEct-MS</a> clinical study</a>, higher doses of temelimab will be evaluated to explore the potential for an even greater effect than the 18 mg/kg dose that provided positive results in the CHANGE-MS and ANGEL-MS clinical studies. The study will enroll a homogenous cohort of 40 MS patients whose disability is progressing without having relapses, based on prior treatment with the anti-CD20 drug rituximab, a highly potent and efficacious drug against acute disease activity (relapses and brain lesion formation). The study's objective, using the latest biomarkers associated with disease progression, is to further explore temelimab's capacity to address this huge unmet medical need in MS.

"As current disease-modifying drugs have limited impact on neurodegeneration, novel therapeutic approaches are needed to modify this main pathogenetic driver for long-term disability in persons with MS" said Professor David Leppert, GeNeuro's Chief Medical Officer. "We are excited to conduct the ProTEct-MS study with the Karolinska Institutet's ASC and its lead investigator, Prof. Fredrik Piehl, to further explore the impact of temelimab on disease progression."

## **About ProTEct-MS**

GeNeuro's ProTEct-MS study is a one-year, single center Phase II clinical trial with higher doses of temelimab in MS conducted by the Karolinska Institutet's Academic Specialist Center (ASC). Initially, 40 patients whose disability progresses without relapses will be enrolled. The 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.

#### **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

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