

GeNeuro's ProTECT-MS Phase 2 trial data, presented at the ECTRIMS 2022 Congress in Amsterdam, confirms synergistic neuroprotective potential of temelimab in MS

- Excellent safety profile and tolerability of higher doses of temelimab
- Synergistic potential to treat neurodegeneration in addition to high-efficacy anti-inflammatory therapy in multiple sclerosis
- Exploratory CSF biomarkers confirm MRI efficacy observations

Geneva, Switzerland, October 28, 2022 – 7:30 am CEST – 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), amyotrophic lateral sclerosis (ALS) and Post-Acute Sequelae of COVID-19 (PASC, long-COVID or post-COVID), today announced that the primary analysis of the Phase 2 ProTECT-MS study was presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2022) Congress in Amsterdam, Netherlands, by Dr. Fredrik Piehl, Professor of Neurology at the Department of Clinical Neurosciences of the Karolinska Institutet, head of research at the MS clinic of the Academic Specialist Center (ASC), and Principal Investigator of the study.

The ProTECT-MS study enrolled a very homogenous cohort of 42 patients being treated with temelimab (18, 36 and 54mg/kg) vs. placebo for 48 weeks. The 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 relapses and brain lesion formation. The one-year Phase 2 trial, conducted at the Karolinska Institutet's ASC in Stockholm, Sweden, evaluated the administration of temelimab in patients with relapsing remitting MS to address disease progression independent of relapses following treatment with rituximab.

The data presented showed that, after one year of treatment, temelimab appeared to be a safe add-on to anti-CD20 treatment. The drug was well tolerated with no treatment related discontinuations, no serious or severe treatment emergent adverse events, and no differences in overall clinical or laboratory safety findings, which meets the primary endpoint of the study.

Also, as already announced in the top-line results in March 2022, MRI biomarkers showed a favourable impact of temelimab in preserving neocortical anatomy and myelin integrity. The effect sizes were of comparable magnitude to those previously observed in the prior CHANGE-MS and ANGEL-MS trials. The combined treatment of temelimab and rituximab protected against loss of cortical thickness by more than 50% relative to rituximab alone. Furthermore, cortical tissue integrity, as measured by magnetization transfer saturation, was improved with temelimab, potentially reflecting remyelination.

New exploratory data was presented on soluble biomarkers, as measures of neurodegeneration at one year: the study showed a reduction of GFAP and NfL biomarkers in cerebrospinal fluid (CSF). GFAP is a biomarker for astrocytic activation associated with diffuse neuroaxonal damage leading to MS disease progression. Patients treated with temelimab and rituximab after 48 weeks showed an average 2.5% reduction in GFAP, versus an average increase of 2.5% for those only receiving rituximab. NfL measurement in CSF, another well-established marker of neuroaxonal damage in MS correlating with MS disease evolution, also showed a relative reduction of 33% in patients treated with temelimab and rituximab, compared to those patients treated with rituximab alone. The results on these CSF biomarkers

confirm the synergistic potential to treat neurodegeneration with temelimab in addition to a high-efficacy anti-inflammatory therapy in MS.

“We are excited by the results of the ProTECT-MS trial as an important step forward for temelimab in its path to treat MS patients in whom disability progresses despite effective control of inflammation and relapses, which is the critical unmet need with current treatment options,” commented Prof. David Leppert, M.D., Chief Medical Officer of GeNeuro. “We thank all the study participants for their time and commitment to this important research effort, especially in the difficult circumstances of the pandemic during the past two years. We are also very grateful for the Karolinska Institutet’s Academic Specialist Center team whose dedication and commitment made this study possible.”

About temelimab

Temelimab is a monoclonal antibody designed to neutralize the W-ENV protein, which is encoded by a member of the Human Endogenous Retrovirus W family. W-ENV is a pathogenic protein, only found in disease situations, and is thought to play an important role in MS by fuelling the mechanisms of neurodegeneration in the brain of patients. The observation of the W-ENV protein in the blood of long-COVID-19 patients long after the primary infection is also thought to be a key mechanism for the development of neurological and psychiatric syndromes that affect many long-COVID patients.

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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