

New data supporting a new precision medicine approach for ALS patients with GeNeuro's GNK-301 presented at the 35th International Symposium on ALS/MND.

Geneva, Switzerland, December 6, 2024 – 6:30 pm CET – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company focused on addressing the factors driving the progression of neurodegenerative and autoimmune diseases, such as amyotrophic lateral sclerosis (ALS), today announced that groundbreaking findings on a potential precision medicine strategy for ALS with GeNeuro's GNK-301 were presented at the 35th International Symposium on ALS/MND, taking place in Montreal, Canada, from December 6-8, 2024. The presentation was delivered by Dr. Darshan Pandya, from National Institute of Neurological Disorders and Stroke (NINDS)/National Institutes of Health (NIH).

The research, led by GeNeuro, through its Lyon R&D unit GeNeuro Innovation SAS, in collaboration with leading institutions, including the NIH/NINDS, ERBC (France), and the University of Oxford (UK), highlights the potential of GeNeuro's GNK-301, a humanized monoclonal antibody targeting HERV-K ENV, a neurotoxic protein that is often found in the cerebrospinal fluid of ALS patients. This protein has been shown to contribute to neuronal cell death and blood-brain barrier dysfunction, two hallmarks of ALS. Preclinical studies have shown that GNK-301 can be used to detect the presence of the HERV-K ENV protein in a laboratory test and that it can then be used as a medicine to neutralize the harmful effects of HERV-K ENV, protecting neurons and preventing damage to the blood-brain barrier. By being able to detect this toxic protein in ALS patients and starting a neutralising treatment early, GeNeuro is proposing a new precision medicine approach that offers hope for transforming the treatment of ALS.

"We are excited to share these promising findings and congratulate the NIH/NINDS, ERBC and the University of Oxford for this exciting new data that opens a path towards a novel precision medicine approach in the treatment of sporadic ALS", said **Hervé Perron, CSO of GeNeuro.**

About GNK-301 and HERV-K ENV

Studies have shown that the HERV-K ENV protein acts as a neurotoxin, contributing to neuronal cell death and blood-brain barrier (BBB) dysfunction—two hallmarks of ALS pathology. In the laboratory, a test with GNK-301 is able to confirm the presence of HERV-K ENV in samples of cerebrospinal fluid (CSF) of ALS patients and, as a consequence, identify those who would benefit from its administration as a medicine. As a neutralizing monoclonal antibody-based medicine, GNK-301 abolishes the ALS CSF neurotoxicity in iPSC-derived neuron cultures and the neuronal death in mice that had been stereotaxically injected with HERV-K ENV. Surprisingly, when present in the brain, the HERV-K ENV protein reproduced the previously reported BBB dysfunction observed in ALS brains, which was also prevented by GNK-301. In animal facilities of ERBC-Voxcan (France), when labelled GNK-301 was injected intravenously in mice, it was found only to accumulate in parts of the brain where HERV-K ENV protein was present. It is of note that there have been previous studies supporting the use of GNK-301 as a medicine: individuals with ALS who make their own endogenous autoantibodies against HERV-K ENV live for longer. However, GNK-301, compared to autoantibodies, has the huge advantage of displaying a much greater affinity and neutralizing effect. In addition, the observed effect of this endogenous neurotoxin on the BBB helps to facilitate the transport of the antibody into brain tissue after its intravenous administration. Further preclinical studies are being conducted, but planning for the required medical grade production of GNK-301 is underway to provide the antibody for clinical studies in ALS patients who will have tested positive for HERV-K ENV with GeNeuro's dedicated immunoassay. This would be the first integrated strategy for precision medicine in sporadic ALS.

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.

For more information, visit: www.geneuro.com



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