Press release

GeNeuro: Frontiers in Genetics review supports role of hidden DNA viruses in neurological disorders

- Human Endogenous Retroviruses linked to MS, Type 1 diabetes, ALS, schizophrenia
- GeNeuro's temelimab most advanced drug candidate targeting pathogenic HERV

Geneva, Switzerland, 11 July 2019 – 6:00pm CEST – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurodegenerative and autoimmune diseases such as multiple sclerosis (MS) and type-1 diabetes (T1D), announced today publication of a review in Frontiers in Genetics, which has compiled growing evidence of the link between human endogenous retroviruses (HERVs) and many difficult to treat neurological disorders. Although completely incorporated into human DNA millions of years ago, HERVs now represent approximately 8% of the human genome. HERV genes are normally silent but have retained the capacity to be activated and upregulated.

The review, titled "Neural cell responses upon exposure to human endogenous retroviruses," highlights the role that environmental factors, such as infection, inflammation, mutations, drugs or infection with other viruses could play in the well-established epidemiological link between HERVs and neurological disorders. Interestingly, HERV transcription and occasional expression of proteins does not always play a biological role. Pathogenic properties are seen when expression of certain HERV proteins abnormally interacts with cellular receptors or with the immune system leading to cytotoxic effects and/or to inflammation and immune dysregulation.

The review describes part of the early development and subsequent start of clinical development of GeNeuro's temelimab, the only drug candidate in MS clinical studies targeting HERVs. The results from the CHANGE-MS and ANGEL-MS Phase 2b trials in patients with relapsing remitting MS showed that treatment with temelimab provided consistent neuroprotective effects on MRI measures known to be associated with disability progression in MS, such as brain atrophy, T1 Black Holes (a measure of permanent damage) or myelin integrity. Temelimab is a monoclonal antibody that neutralizes pHERV-W Env, a pathogenic protein closely linked with MS.

"This review continues to build the evidence showing the link between HERVs, the environmental triggers inducing their pathogenic protein progeny and the development of neurological or autoimmune disorders, such as MS, ALS and Type 1 diabetes," explained lead author Prof. Dr. Patrick Küry Dept. of Neurology, Medical Faculty, Heinrich-Heine-University, Düsseldorf, Germany. "In particularly, these pathogenic proteins are now being exploited as targets for therapeutic intervention, such as with temelimab in MS."

"Research in the HERV field is growing exponentially. This review summarizes the current status of the field which our team has been pioneering for more than 25 years," explained Hervé Perron, PhD, Chief Scientific Officer of GeNeuro. "Our research at GeNeuro continues to build clinical understanding of the pHERV-W Env neutralizing effects of temelimab, particularly with respect to the neuroprotective outcomes in MS, as well as its role in Type 1 diabetes and chronic inflammatory demyelinating polyneuropathy. We are also exploring therapeutic strategies addressing other members of the HERV family, including HERV- K in ALS."

About Temelimab

The development of temelimab (GNbAC1) is the result of more than 25 years of research into human endogenous retroviruses (HERVs), including 15 years within Institut Mérieux and INSERM before GeNeuro was founded in 2006. HERVs are present in the human genome and some have been associated with various auto-immune diseases. The viral envelope protein encoded by a HERV in the HERV-W family (pHERV-W Env) has been found in the brains MS patients, and particularly in active lesions, as well as in the pancreas of patients with in type-1 diabetes on pathological examination. By neutralizing pHERV-W Env, temelimab could simultaneously block a pathological, neurodegenerative process and help to restore myelin integrity in MS patients, as well as to maintain insulin production in T1D patients. Given that the pHERV-W Env protein has no known physiological function, temelimab was expected to have a good safety and tolerability profile, with no effect on the patient's immune system, and importantly this has been borne out by all clinical trials carried out to date.

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 24 employees and rights to 17 patent families protecting its technology.

For more information, visit: www.geneuro.com

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