Press release

GeNeuro Receives Orphan Drug Designation from the US FDA for GNbAC1 in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- GNbAC1 targets pHERV-W env, which is found in half of CIDP patients
- Forthcoming discussions expected with the FDA for the design of a proof-of-concept Phase 2 clinical study

Geneva, Switzerland, 22 February, 2018 – 6:30pm CET – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurological and autoimmune diseases, announced today that GNbAC1 received Orphan Drug Designation (ODD) from the US Food and Drug Administration (FDA) in the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP), a rare autoimmune neurological disorder of the peripheral nervous system. In the US, the prevalence rate of CIDP is estimated to be 9 cases per 100,000. Current long-term therapy is often limited by side effects and one-third of patients are refractory to existing treatments.

GNbAC1 is a monoclonal antibody designed to neutralize a pathogenic, viral envelope protein, encoded by a member of the Human Endogenous Retrovirus-W family, pHERV-W. This protein is thought to be a causal factor in several diseases, including multiple sclerosis, Type 1 diabetes and CIDP. GeNeuro will now start discussions with the FDA for the design of a proof of concept Phase 2 clinical study in this indication.

"This Orphan Drug Designation provides additional validation to our scientific approach to neurological disorders. CIDP is one of several diseases, such as Multiple Sclerosis and Type 1 diabetes, in which pathogenic pHERV-W env has been determined to be a potential causal factor. In CIDP, it has been observed that pHERV-W env is found in approximately half of patients and impairs the integrity of Schwann cells, which maintain the myelin sheath around peripheral nerves, through the induction of IL6 and of CXCL10 that locally recruit inflammatory cells and inhibit remyelination. By neutralizing the activity of this protein, it is expected that GNbAC1 would reduce local inflammation and restore remyelination, with the objective to improve function in affected peripheral nerves," said **Dr. François Curtin, Chief Operating Officer**.

"Receiving Orphan Drug Designation in CIDP provides additional incentive to accelerate studies with GNbAC1 beyond our ongoing Multiple Sclerosis and Type 1 diabetes trials," **said Jesús Martin-Garcia, CEO of GeNeuro.** "*We are grateful for this Orphan Drug Designation and look forward to start interacting with the FDA to plan a clinical development path forward so that a novel therapy could be made available to this patient population who have few effective treatment options*."

Orphan Drug Designation is granted by the FDA to novel therapeutics for diseases or conditions affecting fewer than 200,000 patients in the US or greater than 200,000 patients if there is no reasonable expectation that the production cost of the drug will be covered by its sales. The designation allows the drug developer to be eligible for a seven-year period of US marketing exclusivity upon approval of the drug, as well as, in some cases, tax credits for clinical research costs, the ability to apply for annual grant funding, clinical trial design assistance, and the waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

About CIDP

Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is a rare autoimmune disorder of the peripheral nervous system (PNS) characterized by the destruction of the fatty protective covering (myelin sheath) around nerves due to local inflammation of the nerve roots. As transmission of nerves signals are affected, patients suffer from weakness and impairment of motor function, particularly in the arms and

legs. Some sensory disturbances could also be experienced. CIDP is related to multifocal inflammation and demyelinating lesions of the proximal PNS. Its clinical presentation is heterogeneous and its diagnosis is challenging because of its unknown etiology and the lack of specific biomarkers. Existing CIDP therapies are intravenous human immunoglobulins (IVIG), corticosteroids and plasma exchange. Long-term therapy is often limited by side effects and one-third of patients are refractory to existing treatments. This illustrates a critical unmet medical need for new treatments of CIDP and diagnostic biomarkers in this indication. In the PNS, Schwann cells play a central physiological role. Whilst they are the myelinating cells of the PNS, they can also get activated by pathogenic agents to recruit proinflammatory immune cells. Several studies have confirmed that pHERV-W env is found in half of CIDP patients and that this protein is expressed on Schwann cells in CIDP lesions. The effects of pHERV-W env expression have been studied *in vitro* on cultured human Schwann cells. Cells expressing pHERV-W env presented a strong and significant increase in IL-6 and CXCL10 transcript levels, which are both pro-inflammatory. In the US, based on a prevalence rate of 9 cases per 100,000, the total estimated prevalence of CIDP in 2010 was 27,810 patients.

About GNbAC1

The development of GNbAC1 is the result of more than 25 years of research into human endogenous retroviruses (HERVs), including 15 years at Institut Mérieux and INSERM, a French national medical research institute. Found in the human genome, certain HERVs have been linked to various autoimmune and neurodegenerative diseases. Researchers have demonstrated that the retroviral envelope protein associated with a pathogenic form of HERV-W (pHERV-W, formerly referred to as the Multiple Sclerosis RetroVirus [MSRV]) has been identified in brain lesions of patients with MS, particularly in active lesions, and in the pancreas of Type 1 diabetes patients. By neutralizing pHERV-W env, GNbAC1 could at the same time block these pathological inflammatory processes and restore remyelination in MS patients and maintain insulin production in T1D patients. As pHERV-W env has no known physiological function, GNbAC1 is expected to have a good safety and tolerability profile, without directly affecting the patient's immune system, as observed in all clinical trials to date.

About GeNeuro

GeNeuro's mission is to develop safe and effective treatments against neurological disorders and autoimmune diseases, such as multiple sclerosis or Type 1 Diabetes, 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 31 employees and rights to 16 patent families protecting its technology.

For more information, visit: www.geneuro.com

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