

GeNeuro Presents Data Supporting Role of Human Endogenous Retroviruses (HERVs) in Type 1 Diabetes at American Diabetes Association (ADA) Scientific Sessions

- Data presented suggest pathogenic HERV-W envelope (Env) protein to be potential causal factor in Type 1 diabetes
- Significant expression of pathogenic HERV-W Env found in pancreas of over 50% of Type 1 diabetes patients
- GNBAC1, a humanized mAb targeting HERV-W Env, currently in Phase 2 study in Type 1 diabetes

Geneuro, Switzerland, 12 June 2017 - 7:30am CEST - GeNeuro S.A. (Euronext Paris: CH0308403085 – GNRO), a biopharmaceutical company developing new treatments for neurological disorders and autoimmune diseases, announced today data supporting the link between human endogenous retroviruses (HERVs) and Type 1 diabetes (T1D). Data were presented at the 77th Scientific Sessions of the American Diabetes Association in San Diego, USA (June 9-13, 2017).

HERVs are ancestral, pro-viral, genetic elements, currently estimated to account for 8% of the human genome. Most HERVs are repressed, however in certain susceptible individuals, under pathological conditions, they can be transactivated and the resulting viral proteins appear to play a causal role in several autoimmune and neurodegenerative diseases.

“Our data presented at ADA2017 support the involvement of pathogenic HERV-Env protein in the recruitment of immune cells within the pancreas of human T1D patients and transgenic mice, leading to reduced levels of insulin in the blood,” said Hervé Perron, Chief Scientific Officer of GeNeuro. “Interestingly, the activation of the pathogenic HERV-W Env in human cells can be triggered by enterovirus infections, such as certain strains of Coxsackievirus B4. GeNeuro is in Phase 2 clinical development with GNBAC1, a humanized, monoclonal antibody (mAb) designed to neutralise this protein, in both MS and T1D.”

[Immuno-histological analyses](#) of human pancreas from T1D patients demonstrated that HERV-W expression correlated to macrophage infiltrates ($P < 0.01$) and independently clustered with T-lymphocyte infiltrates. *In vitro*, HERV-W Env directly inhibited glucose-induced insulin release in cultured human beta cells in a dose-dependent manner. In a pathogenic HERV-W Env transgenic mouse model, immune cell infiltrates were found in the pancreas ($P < 0.01$) resulting in significant hyperglycemia and reduced insulin production.

[Data](#) from human Hep2 cells, infected with Coxsackievirus (CV-B4E2 strain) isolated from a T1D pancreas, resulted in significant upregulation of HERV-W-Env mRNA transcription compared to non-infected cells ($p < 0.001$ at MOI=10-2; $p < 0.05$ at MOI=10-5). This effect was not observed with the CV-B4 strain (not isolated from T1D pancreas), suggesting a strain specific effect.

About GNBAC1 Type 1 Diabetes Study

This randomized, placebo-controlled Phase 2a study will evaluate the safety of GNBAC1 in 60 adults recently diagnosed with T1D. Secondary endpoints will measure the correlation between treatment response and pathogenic HERV-W Env biomarkers. Treatment response will be assessed by insulin production (as measured by C-peptide), insulin consumption, glycemia and production of anti-beta cell antibodies. Enrolment is expected to complete by the end of 2017, with data expected in the third quarter of 2018.

About Type 1 Diabetes

Type 1 diabetes (T1D), commonly diagnosed in childhood, is thought to be caused by an immune response directed against the insulin producing cells of the pancreas. There is no cure for T1D and patients require life-long insulin replacement therapy. T1D is associated with several debilitating complications, including heart disease, blindness, neuropathy and kidney disease, among others.

About GNbAC1

The development of GNbAC1 is the result of 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, HERV-encoded proteins have been linked to several autoimmune and neurodegenerative diseases. Researchers have demonstrated that the envelope protein (Env) encoded by a pathogenic HERV-W, first identified in active lesions in post-mortem brains of patients with MS, has also been found in the pancreas of T1D patients. By neutralising pathogenic HERV-W Env, GNbAC1 has the potential to block pathological inflammatory processes, restore remyelination in MS patients and maintain insulin production in T1D patients. As pathogenic HERV-W Env has no known physiological function, GNbAC1 is expected to have a good safety profile, without affecting the patient's immune system, as has been observed in clinical trials to date.

About GeNeuro

GeNeuro's mission is to develop safe and effective treatments against neurodegenerative 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 France at sites in Archamps, Haute-Savoie and in Lyon. It has 30 employees and rights to 16 patent families protecting its technology.

For more information, visit: www.geneuro.com

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