

## GeNeuro's Temelimab Phase IIa Data in Type 1 Diabetes at 12 Months Confirms RAINBOW Positive Results

- Study meets objective of demonstrating safety and pharmacodynamic response
- Confirmed excellent safety profile in combination with concomitant medications, with no serious adverse events
- Opens way for further development in early-onset pediatric population

**Geneva, Switzerland, 7 May 2019 – 7:30am 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), today announced that a six-month extension of its Phase IIa study of temelimab (GNbAC1) in T1D confirmed all previously-observed positive observations in the trial, meeting its primary objective. GeNeuro believes these data open the door to further development in early-onset T1D pediatric patient population.

In the extension, all patients were treated with temelimab, including those previously on placebo. Data confirmed a very strong safety profile, with no serious related adverse events over the one-year study period, and a continued benefit on the number of hypoglycemic events. The positive effects observed in the 6-month double-blind placebo-controlled period were extended to those patients who switched to temelimab from placebo in the open-label extension period. Pharmacodynamic (PD) markers, such as anti-insulin antibodies, also improved once the placebo population switched to temelimab.

*“These excellent results further expand the solid set of positive clinical data we have compiled on temelimab. It also provides more evidence for our approach in targeting pHERV-W Env in combination with concomitant medications in a new therapeutic setting. Temelimab is a very promising drug candidate with the potential to significantly improve the lives of patients not only with T1D, but also multiple sclerosis, where we have seen exciting evidence of neuroprotection. Based on these results, we will explore further clinical development in T1D, where we aim to test this potential disease modifying approach in larger early-onset populations,”* said Jesús Martín-García, CEO of GeNeuro.

Temelimab is a monoclonal antibody designed to neutralize a pathogenic envelope protein, pHERV-W Env, encoded by a member of the Human Endogenous Retrovirus W family. This protein has been detected post mortem in about two thirds of the pancreas of patients with T1D, its toxicity on the pancreas has been validated in preclinical models, and it is thought to be a key factor in the onset and development of the disease. Neutralizing the toxicity induced by pHERV-W Env in the pancreas may provide a specific and safe disease modifying therapy for T1D patients.

The Phase IIa randomized, placebo-controlled, safety and signal finding study (RAINBOW) evaluated temelimab in 64 adult patients diagnosed with T1D for up to 4 years, in 12 centers in Australia. The primary endpoint of the study was safety of temelimab administration in combination with T1D treatments. Secondary endpoints measured T1D biomarkers such as HbA1c, C-peptide levels, and other biomarkers associated with T1D, such as insulin consumption, glycaemia and production of diabetic auto-antibodies.

The well-controlled adult and late onset population in the study had been treated effectively and had low insulin needs and stable HbA1c and C-peptide levels, which remained stable during the trial. The group treated with temelimab for 12 months showed reduction of frequencies of hypoglycemic episodes under temelimab treatment in the initial 6-month double-blind phase (-28%,  $p < 0.001$  versus placebo), and a further reduction of 10% of hypoglycemic episodes in the second 6-month period. The group switching to temelimab from placebo showed reduction of the frequency of hypoglycemic episodes versus the previous placebo period (-29%), reaching the level of reduction observed with temelimab in the group treated for the first 6 months.

The small cohort size and low occurrence of events confirm excellent tolerability but do not allow for definitive efficacy conclusions.

## About Type 1 Diabetes

Type 1 diabetes, usually first diagnosed in children, is caused by an immune response directed against the insulin producing cells of the pancreas. There is no cure for this 'autoimmune' disease, which means patients need life-long treatment with insulin replacement. This treatment is often associated with several debilitating complications, including heart disease, blindness, and kidney disease, among others.

## 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 27 employees and rights to 17 patent families protecting its technology.

For more information, visit: [www.geneuro.com](http://www.geneuro.com)

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