Press release

GeNeuro Announces Positive Results from Temelimab (GNbAC1) Phase 1 High-dose Clinical Trial

International Nonproprietary Name "temelimab" Assigned to GNbAC1

- Temelimab's robust safety and tolerability profile confirmed
- High-dose regimen fully validated by pharmacokinetic data
- Enables higher doses or front-loading to be considered for future clinical studies
- Drug candidate's overall profile enhanced ahead of a possible partnership to continue the global development of temelimab as a treatment for multiple sclerosis (MS)
- International Nonproprietary Name "temelimab" assigned by the WHO for GNbAC1

Geneva, Switzerland, 21 January 2019 – 6.00pm CET – GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurological and autoimmune diseases such as multiple sclerosis (MS) and type-1 diabetes, today announced positive safety and tolerability results from a Phase 1 study assessing the administration of high doses of temelimab (GNbAC1) to treat MS and other auto-immune diseases.

In this randomised, double-blind and placebo-controlled study of 24 healthy volunteers, four cohorts received doses of GNbAC1 ranging from 36 mg/kg to 110 mg/kg. The results of the study showed that no adverse events related to drug safety occurred and that pharmacokinetic data were linear for all doses tested.

The study builds on data from the CHANGE-MS Phase 2b trial, which demonstrated that only the highest dose tested, 18 mg/kg, was effective. These results suggest that higher dose regimens or a front-loading could be evaluated in the next clinical study of temelimab in MS and other potential therapeutic indications.

In addition, GeNeuro confirmed that the World Health Organization (WHO) has assigned the International Nonproprietary Name (INN) "temelimab" to GNbAC1

Jesús Martin-Garcia, Chairman and CEO of GeNeuro, said: *"The results from this high-dose study support and expand the large amount of positive clinical data we already have regarding temelimab's safety, tolerability and efficacy. Temelimab is the first treatment targeting an MS mechanism to have shown robust and consistent effects on key neuroprotection markers in clinical trials. The success of this Phase 1 study allows us to explore whether higher doses of temelimab provides additional benefit in MS patients as well as broadening the therapeutic areas for which this drug candidate could be used."*

In October 2018, in the Congress of the European Committee for Treatment and Research on Multiple Sclerosis held in Berlin (ECTRIMS 2018), GeNeuro announced that final analysis of the Phase 2b CHANGE-MS clinical study had produced robust results regarding key markers related to MS progression, and that the effects were greater in patients who did not experience inflammatory activity during the study. These patients represent precisely the group of MS sufferers who are not well served by currently available therapies. The CHANGE-MS results suggest temelimab has the potential to become a totally new mechanism of action targeting a cause of MS progression. Furthermore, they suggest that temelimab could be used as a single agent in patients suffering from progressive MS without active inflammation, or synergistically with existing anti-inflammation MS drugs.

As previously disclosed, GeNeuro is continuing discussions with potential partners to define next steps in developing temelimab for MS, while moving forward with its programmes in type-1 diabetes and amyotrophic lateral sclerosis. The recent signature of a financing agreement with GNEH, a subsidiary of Institut Mérieux, means that GeNeuro can cover all of its current programmes as well as its operating expenses until at least mid-2020.

About Temelimab

The development of temelimab (GNbAC1) is the result of 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 MS patients and particularly in active lesions, as well as in the pancreas in type-1 diabetes patients. By neutralising pHERV-W Env, temelimab could simultaneously block the pathological inflammation process and restore the remyelination process in MS patients, and maintain insulin production in type-1 diabetes patients. Since the pHERV-W Env protein has no known physiological function, temelimab should have a good safety profile, with no effect on the patient's immune system: 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 27 employees and rights to 17 patent families protecting its technology.

For more information, visit: www.geneuro.com

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