

GeNeuro and FondaMental Foundation announce the first results of the collaboration for the development of diagnostic and therapeutic options for patients with post-COVID neuropsychiatric syndromes

- The study shows a strong correlation between SARS-CoV-2 infection, W-ENV protein and markers of innate immunity, in patients with psychiatric disorders
- The results confirm the interest of treating post-COVID neuropsychiatric syndromes by neutralizing the W-ENV protein with the temelimab antibody
- GeNeuro is preparing to launch a phase 2 clinical trial in 200 patients with post-COVID syndromes and positive for W-ENV

Geneva, Switzerland, April 13, 2022 - 7:30 am CEST - GeNeuro (Euronext Paris: CH0308403085 - GNRO), a biopharmaceutical company developing new treatments for neurodegenerative and autoimmune diseases, such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and the severe neuropsychiatric consequences of COVID-19 (post-COVID), and the FondaMental Foundation, a scientific cooperation foundation serving patients with mental illness, presented at the Schizophrenia International Research Society (SIRS) congress from April 6 to 10 in Florence, Italy, the first data resulting from their collaboration launched in 2021, in the context of COVID.

These results were presented during the session entitled "**Human Endogenous Retrovirus (HERV) as a Missing Link between Inflammation and Schizophrenia in the Context of COVID**" with presentations by Prof. Marion Leboyer (Université Paris-Est-Créteil, Hôpital H. Mondor, FondaMental Foundation, Créteil, France), Dr. Livia de Picker (University of Antwerp, Belgium), Prof. Urs Meyer (University of Zurich, Switzerland) and Dr. Hervé Perron (GeNeuro), and concluded by Prof. Robert Yolken (Johns Hopkins University, Baltimore, USA).

The first results presented in Florence were based on the analysis of blood samples from 104 patients hospitalized between January and March 2021 for psychiatric disorders, either for the first time or because of relapses, in the psychiatry department of Prof. Leboyer in Créteil at Hôpital H. Mondor, and 63 controls.

The objective of this analysis was to measure the coronavirus infection rate in a population with no reported COVID disease and to search for links between SARS-CoV-2 infection and the endogenous retroviral protein W-ENV. The analyses were performed by the INSERM "We-Met" platform at the Paul Sabatier University in Toulouse.

SARS-CoV-2 specific serological analyses showed that 82% of the patients admitted to the psychiatric ward had been exposed to the COVID-19 virus. The detection of W-ENV protein was positive in the serum of 40% of the patients studied, but almost exclusively and very significantly in patients seropositive for SARS-CoV-2 ($p < 0.01$). The presence of W-ENV protein in the blood was also strongly correlated with elevated levels of cytokines characteristic of innate inflammation such as TNF- α , IL-1 β or IL8 ($p < 0.0001$ for all three).

"We have repeatedly, in [independent cohorts](#), shown the presence of W-ENV protein in blood samples of patients with psychotic spectrum disorders and chronic systemic inflammation," said Prof. Marion Leboyer, Director of the Department of Psychiatry at Henri Mondor University Hospitals (Université Paris Est Créteil) and Director of the FondaMental Foundation. "The results of our study in these patients hospitalized during the COVID-19 pandemic revealed that most of them had been exposed to SARS-CoV-2. These data reinforce the interest of a personalized therapeutic approach in W-ENV positive patients against neuropsychiatric syndromes in the post-COVID-19 context."

Studies published in 2021 had shown that W-ENV expression was [triggered by SARS-CoV-2](#) in the white blood cells and tissues of about 20% of healthy donors, suggesting individual susceptibility. This protein was also detected in the blood of hospitalized COVID-19 patients where the amount of expression in lymphocytes was associated with [disease progression severity](#). The persistence of W-ENV expression long after the acute phase of the disease and its association with immunoinflammatory manifestations support the biological hypothesis of its importance in the long-term neuropsychiatric syndromes suffered by many post-COVID patients.

"The action of the W-ENV protein on innate inflammation and its deleterious action on cells of the nervous system have been documented over the last 20 years," add Dr. Hervé Perron, Chief Scientific Officer of GeNeuro. "Post-COVID is characterized by a wide range of symptoms, with probably a multifactorial origin. But the ability to detect W-ENV in post-COVID patients with neuropsychiatric disorders allows to identify a well-defined group of patients that we can rapidly treat with the aim of improving their condition by neutralizing this pathogenic protein.

GeNeuro has developed temelimab, a specific antibody against the W-ENV protein, which has shown promising results in Phase II trials in multiple sclerosis against MRI markers of neurodegeneration. Temelimab has shown excellent safety and tolerability in several hundred patients treated for 2 years or more. GeNeuro is preparing to launch a clinical trial in 200 W-ENV positive patients with post-COVID neuropsychiatric syndromes. This clinical trial is co-financed by the Swiss Federal Office of Public Health.

About GeNeuro

GeNeuro's mission is to develop safe and effective treatments for neurological disorders and autoimmune diseases, such as multiple sclerosis, by neutralizing the causative factors encoded by HERVs, which represent 8% of human DNA.

GeNeuro is headquartered in Geneva, Switzerland, and has R&D facilities in Lyon, France. It has rights to 17 patent families protecting its technology.

For more information, please visit: www.geneuro.com

About the FondaMental Foundation

The FondaMental Foundation is a scientific cooperation foundation, located at the Albert Chenevier Hospital, Créteil (France). Its mission is to innovate in the organization of care, to support research and innovation in the service of mental illnesses, to deploy training and to improve information to reduce stigma.

For more information, please visit: www.fondation-fondamental.org

Press Contacts :

FondaMental Foundation:
Laurence de la Touche / +33 6 09 11 11 32 - laurence@agencethedesk.com

GeNeuro :
Arthur Rouillé / +33 (0)1 44 71 00 15 - arouille@newcap.fr

GeNeuro contacts

GeNeuro

Jesús Martin-Garcia
President and CEO
+41 22 552 4800
investors@geneuro.com

NewCap (France)

Mathilde Bohin / Louis-Victor Delouvrier (investors)
+33 1 44 71 98 52
Arthur Rouillé (media)
+33 1 44 71 94 98
geneuro@newcap.eu

Disclaimer

This press release contains certain forward-looking statements and estimates about GeNeuro's future financial condition, results of operations, strategy, plans and performance and the markets in which it operates. These forward-looking statements and estimates can be identified by words such as "anticipate," "believe," "may," "estimate," "expect," "intend," "is designed to," "may," "could," "plan," "potential," "predict," "objective," "should," or the negative of these terms and other similar expressions. They include all matters that are not historical facts. Forward-looking statements, forecasts and estimates are based on management's current assumptions and assessment of known and unknown risks, uncertainties and other factors that were believed to be reasonable at the time they were made but may prove to be incorrect. Events and results are difficult to predict and depend on factors beyond the Company's control. Consequently, the actual results, financial condition, performance and/or achievements of GeNeuro or the industry may differ materially from future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Because of these uncertainties, no representation is made as to the accuracy or correctness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates speak only as of the date they are made, and GeNeuro undertakes no obligation to update or revise them, whether as a result of new information, future events or otherwise, except as required by law.