PRESS RELEASE

Nantes, November 12, 2020

#Covid19 #Treatment #Clinical Trial

XAV-19: validation of the first dose of anti-Covid treatment of XENOTHERA and continuation of the POLYCOR clinical trial

A new step for XENOTHERA and the CHU de Nantes in the daily fight against Covid-19 ! The POLYCOR clinical trial continues after the validation by the independent committee (DSMB) of the safety of the first dose of XAV-19 in the first 10 patients. Based on a unique and patented technology for the production of protective polyclonal antibodies similar to the natural human response, this drug candidate is intended for patients with moderate COVID-19-induced pneumonia at the beginning of hospitalization; it aims to halt the worsening of the disease and in particular to avoid a transfer to intensive care.

Launched in September**, the French POLYCOR clinical trial is led by Benjamin Gaborit, MD, PhD, at the Infectious and Tropical Diseases Department of Nantes University Hospital** (Head Professor François Raffi) and involves **four University Hospital Centers (CHU) in France: Nantes, Angers, Paris (Saint-Antoine), and Lyon.**
POLYCOR is being conducted in two phases: Phase IIa is analyzing the safety of XAV-19 in 18 patients at two different doses and is taking place in these four CHU's. Phase IIb will enroll several hundred patients in approximately 40 hospitals.

At the request of the French authorities, the Nantes CHU and XENOTHERA regularly place patients on hold for a systematic review of the safety of XAV-19. **The independent committee, which met on November 4, confirmed the safety of XAV-19 at the first dose tested, based on clinical and biological data from the first 10 patients. This opinion allows the trial to continue.**

The second phase IIa cohort of 8 patients receiving a second dose can now begin. It will be completed within three weeks.

"We are pleased to participate actively in the POLYCOR clinical trial alongside XENOTHERA and to have been able to start the administration of XAV-19 in the first patients infected with SARS-CoV-2 in our University Hospital Center," said **Professor François RAFFI, Head of the Infectiology Department of the Nantes University Hospital.**

"After the authorization of the ANSM last August to start our clinical trial, this first validation of the DSMB is a key step confirming the safety of our drug candidate XAV-19! We are pleased to get progressively closer to the possibility of measuring a benefit for patients. I would like to thank the patients who accept to participate in clinical trials and who are thus participating through a concrete engagement in the fight against the virus", concludes **Odile Duvaux, President of XENOTHERA.**

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About XENOTHERA :
Created in 2014, XENOTHERA is a Nantes-based biotech company that develops "humanized" polyclonal antibodies. Its technological platform is built on a dual expertise in animal genetics and immunology. The company has a complete portfolio of products, the first of which, LIS1, an immunosuppressant in transplantation, has been in the clinic since 2019. XENOTHERA has also developed a treatment against coronavirus infections for both the current pandemic and future infections. Intended for patients at the beginning of hospitalization, this drug candidate named XAV-19 is based on a unique patented antibody production technology, developed and proven over several years by biotech.
XENOTHERA is part of Nantes' scientific, medical and academic environment and has been supported since its creation by public and private investors.
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