PRESS RELEASE

#Covid19 #Treatment #Clinical Trial

XENOTHERA obtains authorization from ANSM to start the clinical trial of XAV-19, its anti-Covid treatment

Nantes, August 10, 2020 – **XENOTHERA, a Nantes-based biotech company, announced today that it has received official authorization from the French National Agency for the Safety of Medicines and Health Products (ANSM) to start the phase 2 human clinical trial of its XAV-19 treatment. The purpose of this clinical trial is to evaluate the safety, therapeutic efficacy and safety of the drug candidate in hospitalized patients with moderate pneumonia induced by COVID-19.**

The anti-COVID treatment developed by XENOTHERA is based on a unique and patented technology for the production of protective polyclonal antibodies similar to the natural human response. Intended for patients at the beginning of hospitalization, it aims to prevent the disease worsening, and to avoid a transfer to intensive care units.

Sponsored by the clinical teams of the Nantes University Hospital, led by Professor François Raffi as part of the POLYCOR consortium, the clinical trial should start in the coming weeks in several French hospitals.

A randomized, double-blind, placebo-controlled study evaluating XAV-19 in patients infected with SARS-CoV-2 will be conducted in two phases: a first analysis (phase 2A) will be performed on about 15 patients to confirm the safety of the treatment. A second stage (phase 2B) will aim to expand the analysis by recruiting several hundred patients. In total, and depending on the possibilities, 350 people should be involved in this clinical trial.

"ANSM's authorization to start our clinical trial is excellent news for the development of our anti-Covid treatment and the fruit of our team's remarkable involvement over the last few months! This essential step, when we are talking about a resurgence of the epidemic, shows the importance of continuing to sustain our efforts. We strongly believe in our treatment, which allows to cure patients at the beginning of their hospitalization, and we are now eager to evaluate it concretely. We will be able to start this clinical trial quickly, particularly thanks to the help of our historical partner the Nantes University Hospital, associated with the University of Nantes," declared **Odile Duvaux, President, and Bernard Vanhove, XENOTHERA's Director of Operations, in a common voice.**

Nota bene:

- A pre-publication on the scientific evidence of XAV-19 was relayed by BioRXiv on July 25, showing in particular that:
- XENOTHERA's antibodies have characteristics that increase their tolerability in humans.
- These antibodies suppress the inflammatory risks that accompany other antibody-based therapies that may occur in patients with COVID-19.
- XENOTHERA's anti-SARS-CoV-2 drug/antibody has demonstrated a strong ability to neutralize the virus in several pre-clinical systems, illustrating its clinical potential.

More information by clicking here.

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About XENOTHERA:
Created in 2014, XENOTHERA is a Nantes-based biotech company which 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 used for transplants, has been in clinical trials since 2019. XENOTHERA is part of the Nantes scientific, medical and academic environment and is supported by the Pays de la Loire region’s Atlanpole competitiveness cluster.
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