



**PRESS INFORMATION**  
Nantes, December 29, 2020

#Covid19 #Treatment #ClinicalTrial

## **New step for XENOTHERA and the Nantes University Hospital: start of phase 2b of the POLYCOR clinical trial of XAV-19 classified as "national research priority"**

The Nantes-based biotech [XENOTHERA](#) and [the Nantes University Hospital](#) announced today the authorization by the ANSM to start phase 2b of the French clinical trial POLYCOR, which tests the therapeutic efficacy of XAV-19, the anti-Covid treatment -19 developed by XENOTHERA. The independent DSMB committee, after having validated the safety of the first dose of XAV-19 in the first 10 patients, has just validated the tolerance of the therapeutic dose and has given its approval for the continuation of the trial. The National Medicines Safety Agency (ANSM) has confirmed its authorization to start this phase 2b. This new phase will bring together 400 patients in more than 40 hospitals in France.

At the same time, the POLYCOR clinical trial has just been awarded the "[national research priority](#)" label by the ad hoc national steering committee for therapeutic trials and other research (CAPNET). This national system makes it possible to identify and prioritize the most promising studies in clinical research on Covid-19.

*"This is a big step for the XAV-19 and a great recognition of our commitment and mobilization! We are finally starting the quantitative part of the trial, which will compare XAV-19 and a placebo. The inclusions are scheduled from this week, to continue until spring 2021. To carry out this clinical trial, since this summer we have had a batch of product of 1000 vials. We have just completed it with a batch of 4000 bottles.",* Declares **Odile Duvaux, President of XENOTHERA.**

Analysis of data in the first 18 patients demonstrated the safety of XAV-19. Pharmacokinetic assays measured its diffusion into the blood of patients, which could confirm the dose and regimen of a single infusion of the product.

XENOTHERA plans to start a **European trial, named EUROXAV**, in **several European countries** in the coming weeks. This so-called "phase II / III" trial will ultimately strengthen the dossier for XAV-19 with a view to its authorization for use in patients.

**Based on a unique and patented technology for producing protective polyclonal antibodies similar to the natural human response, the drug candidate XAV-19 is intended for patients at the beginning of hospitalization with moderate pneumonia induced by COVID-19 ; it aims to stop the worsening of the disease and in particular to avoid a transfer to intensive care.**

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**About POLYCOR:**

POLYCOR, sponsored by Nantes University Hospital, is a French phase II clinical trial aimed at evaluating the safety and efficacy of XAV-19, the anti-COVID19 treatment developed by XENOTHERA. The trial is scheduled to recruit 400 patients from around 40 hospitals. It is headed by Dr Benjamin Gaborit, and Professor François Raffi, from the Nantes University Hospital. POLYCOR was funded in July 2020 in the form of a COVID PSPC bringing together XENOTHERA, the Nantes University Hospital and the University of Nantes. The POLYCOR project received a total allocation of over € 8M from the General Secretariat for Investment.

**About the Nantes University Hospital:**

<https://www.chu-nantes.fr/>

**About XENOTHERA:**

Created in 2014, XENOTHERA is a Nantes-based biotech that develops “glyco-humanized” polyclonal antibodies. Its technological platform is built on a dual expertise of genetics and immunology. The company has a comprehensive product portfolio, the first of which, LIS1, an immunosuppressant in transplantation, has been in the clinic since 2019. XENOTHERA has also been developing its treatment for coronavirus infections for several years. XAV-19 is XENOTHERA's treatment for patients at the start of hospitalization, it is based on a unique patented antibody production technology, developed and proven for several years by biotech. XENOTHERA is part of the scientific and medical environment of Pays de la Loire, and has been supported since its creation by private investors. Since its creation, the company has raised more than 23 million euros in financing for all of its products.

To find out more, please visit: [www.xenothera.com](http://www.xenothera.com)

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