Press release
Nantes, 16 December 2022

- Anti-Covid treatment: EUROXAV clinical trial stopped -

XAV-19: end of EUROXAV clinical trial and positive trends for the XENOTHERA antibody.

Nantes-based biotech XENOTHERA, which develops innovative antibodies in several therapeutic areas, has developed XAV-19, an anti-COVID treatment based on its unique and patented technological platform, since March 2020. XAV-19, a drug candidate to treat patients at the moderate stage of the disease, before respiratory worsening, is a protective polyclonal anti-SARS-CoV-2 antibody similar to the natural human response. The biotech announced today that it is ending its European clinical trial and is reporting initial efficacy data.

EUROXAV is a phase II/III clinical trial which started at the end of April 2021 in Spain, Greece, Bulgaria, Romania and Turkey, with the objective of evaluating the therapeutic efficacy of XAV-19 in patients with moderate COVID. The primary endpoint of the trial was initially defined as respiratory worsening measured by a one-point increase in the WHO score.

The trial, planned to recruit 722 patients, has been experiencing a slowdown in enrolment for several months, with 293 patients enrolled so far. **Facing this situation, the biotech decided on December 12th to terminate the trial for ethical reasons for future patients**. **No safety problems related to the product have been identified** in any of the patients included.

Beyond the safety of the product, the **intermediate efficacy results** have already made it possible to make **some important observations**. First, XAV-19, like other antibodies, does not seem to provide any clinical benefit in oxygen-requiring patients (WHO score 4). At this stage of the disease, inflammatory pathology predominates, and the administration of an anti-SARS-CoV-2 antibody like XAV-19 comes too late. For WHO score 4, the XAV-19 group and the placebo group worsen in the same way (worsening in the order of 6%).

There are **two positive trends indicating the potential therapeutic value of XAV-19 for patients with moderate COVID who are not under oxygen therapy**, whether they are hospitalized (WHO score 3) or not (WHO score 2). On the one hand, the number of aggravations is lower in XAV-19 treated patients (three to four times less aggravations with XAV-19). On the other hand, a more rapid recovery is observed, characterized by a reduction in the WHO score (three times more patients on XAV-19 recover in the first five days after treatment, compared to placebo). All the analyses will be published in a scientific journal in the coming weeks.
Patients with a WHO score of 2 had been sick for 4.49 days, WHO score 3 for 5.42 days, and WHO score 4 for 6.65 days; these data indicate the potential value of administering XAV-19 within the first 5 days of illness, a period similar to that recommended for other antibodies, particularly for patients either immunocompromised for reasons of chronic disease, either not vaccinated, or not responding to vaccination.

Due to the number of patients enrolled in the EUROXAV trial, the limited statistical power requires to confirm these trends in a new clinical trial targeting patients responsive to XAV-19. This project is under study at XENOTHERA.

"First of all, we would like to express our heartfelt thanks to the patients and the healthcare teams, especially the doctors who have invested in this clinical trial. We are pleased to have today very encouraging first data on the benefit of XAV-19 in patients with COVID. As we anticipated, our treatment seems to be of real interest at the moderate stage of COVID, but seems to come too late for severe or critical patients, who are already under oxygen. It is with great regret that we had to make a decision that inherently limited the quality of the findings due to the small number of patients; unfortunately, this is a situation encountered by many laboratories involved in the fight against COVID. However, these first data are promising; the entire XENOTHERA team is proud of these results and of its commitment in this fight, which is not over. In parallel, the company is moving forward with its other projects, in particular the drugs we are developing in cancer and transplantation." comments **Odile Duvaux, CEO and co-founder of XENOTHERA**.

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About EUROXAV:
EUROXAV is a phase II/III clinical trial (NCT04928430) aimed at evaluating the therapeutic value of XAV-19 in patients with moderate COVID. The trial, which started at the end of April 2021 in Spain, Greece, Bulgaria, Romania and Turkey, is publicly funded under the European BRIGHT project, via the SME Acceleration call for proposals (grant agreement no. 962036).

About XENOTHERA:
Founded in 2014, XENOTHERA is a Nantes-based biotech that develops new therapeutic modes in many fields (immunology, oncology, viral infections...). The company develops treatments based on a unique proprietary technology of "glyco-humanised" polyclonal antibodies. Its technological platform is built on a dual expertise in genetics and immunology.
The biotech has a complete portfolio of products, including three products in the clinic: LIS1, an immunosuppressant for solid organ transplantation; XAV-19, an anti-Covid treatment for patients with moderate disease; and XAB05, which is intended for the prevention and treatment of multi-drug resistant bacterial infections.
XENOTHERA, a member of the Atlanpole Biotherapies competitiveness cluster, is part of the scientific and medical environment of the Pays de la Loire (France). The company has been supported since its creation by business angels, private investors, by the Pays de la Loire Region, by BPI France and by the European EIC Fund.
More information: www.xenothera.com
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Media relations:
IZsoGOOD
Ingrid Zémor
+33 6 73 72 99 92
xenothera@izsogood.co