PRESS INFORMATION
Nantes, January 31, 2022

Anti-Covid treatment XAV-19:

The biotechnology company XENOTHERA announces the continuation of development of its anti-SARS-CoV-2 antibody.

This decision follows the last hearing of XENOTHERA by the ANSM and the ANRS-MIE on 25 January and the refusal of its request for early access authorization by the HAS on 28 January 2022.

During the latest exchanges with the agencies, the biotech presented the data in its possession to support its early access application for XAV-19. The proposed indication concerns patients with COVID at the start of the respiratory worsening phase, between 6 and 10 days after the onset of symptoms, whose clinical condition does not require emergency care.

To study the efficacy of its drug candidate, the biotech relied on the analysis, made available at the beginning of January, of a sub-group of patients who participated in the French trial and whose degree of severity was adapted to the objectives of the study. Indeed, the vast majority of patients included in this phase II trial were at too advanced a stage of the disease for a benefit of the treatment to be observed; **it was on a limited number of patients (15% of those included) that the benefit of XAV-19 could be analyzed. This analysis shows a trend in favor of the product, XAV-19 reducing by three the rate of respiratory worsening, from 22% in the placebo group to 7% in the XAV-19 group**. However, the limited number of patients in this subgroup didn't allow the conventional significance threshold of p=0.05 to be passed.

The reassuring information on the safety of the product and its efficacy on the Omicron variant (published in Vanhove et al, BioRxiv, 2022) convinced the agencies that "the continuation of this development seems [...] relevant". In its opinion issued on 28 January, the HAS indicated that the efficacy of this drug in the indication considered "was not strongly presumed". Consequently, **the request for early access for XENOTHERA could not be granted and the agency expressed its expectation that additional clinical data on a larger number of patients would be required. XENOTHERA therefore confirms the continuation of the clinical development plan for XAV-19**.

"My first thought goes to the patients. First of all, to those who participated in the French trial, whom we thank. Secondly, to those for whom there is no therapeutic solution to date, and for whom we have been mobilized since the creation of XENOTHERA. It was our responsibility to submit an early access application on their behalf. Although the data available is limited, we wanted to have the opinion of the authorities to see if they would consider the interest of the product. Their decision is, as I have always said, sovereign, and we of course respect it. In accordance with their advice, we are continuing our European trial to complete the data on the XAV-19, which interest remains unchanged," comments **Odile Duvaux, CEO of XENOTHERA**.

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About XENOTHERA:
Founded in 2014, XENOTHERA is a Nantes-based biotech company that develops new therapeutic methods in many fields (immunology, oncology, viral infections, etc.). The company develops treatments based on a unique proprietary technology for the production of "glyco-humanised" polyclonal antibodies. Its technological platform is built on a dual expertise in genetics and immunology. Several years ago, XENOTHERA identified the value of its antibodies as a treatment for coronavirus infections, which enabled it to propose a drug candidate against Covid at the start of the pandemic: XAV-19. This anti-Covid treatment is intended for patients suffering from moderate forms of the disease; it aims to reduce the risk of aggravation and avoid, in particular, a transfer to intensive care.
The biotech also has a complete portfolio of products, including LIS1, an immunosuppressant in transplantation, which has been in the clinic since 2019, and XAB05, which will enter the clinic in January 2022 and is intended for the treatment and prevention of multi-drug resistant bacteria infections.
XENOTHERA, a member of the Atlanpole Biotherapies competitiveness cluster, is part of the scientific and medical environment of the Pays de la Loire. The company has been supported since its inception by private investors, by the Pays de la Loire Region and by BPI France.

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