PRESS INFORMATION

XENOTHERA receives the Rapid Scientific Advice of the European Medicines Agency (EMA) for XAV-19 Market Authorization

Nantes, July 8th 2021 – **XENOTHERA is a French biotech developing XAV-19, a polyclonal antibody active against SARS-CoV-2, original and variants of concern (Vanhove et al. BioRxiv, 2021) aimed at treating patients suffering from moderate to severe COVID-19. Based on its current package, XENOTHERA has initiated the dialogue with the European Medicines Agency (EMA) early 2021. The Scientific Advice received this week confirms the strategy of the biotech and paves the way for the approval of XAV-19.**

XAV-19 is in clinic since mid-2020. The inclusions of phase IIa (Gaborit et al. AAC, 2021) and IIb are now completed, with 436 patients enrolled in a double-blind randomized trial (Gaborit et al. Trials, 2021), and the first results are expected in the coming weeks. Phase III trial named EUROXAV is currently ongoing in several European countries (Greece, Bulgaria, Romania, and pending Spain) and will enroll 722 patients in a double-blind randomized trial. Results from this pivotal trial are expected in 6 to 8 months.

The Committee for Medicinal Products for Human Use (CHMP) globally endorses the approach presented by XENOTHERA, particularly the quality of XAV-19, the validity of preclinical and toxicology data, and the overall approach of the clinical development plan of XAV-19.

Odile Duvaux, CEO of XENOTHERA, is commenting on this decision : "*This is a first major step for a company the size of XENOTHERA and confirms our credibility and the seriousness of our approach for our anti-COVID19 treatment. EMA has overall endorsed our presentation of XAV-19, and this scientific advice allows us to fine tune our calendar, still targeting MAA in 12 to 18 months. Of note, facts are currently demonstrating that treatments are still urgently needed, beyond vaccines, to solve the major health challenge that this virus has raised worldwide. I think this is also a recognition of the full engagement of the whole team, who has been strongly committed since the beginning of the pandemic in bringing solutions for patients needing care*".

As a reminder, **the French government has pre-ordered the first 30,000 doses of XAV-19 for French patients**. Provided an early access (Autorisation d'Accès Précoce) is granted by the French Haute Autorité de Santé, **these treatments should be at patients' disposal in October 2021**.

XENOTHERA announced last week a fundraising of €20million, where the European Innovation Council Fund has taken a major part.

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About XENOTHERA:

Founded in 2014, XENOTHERA is a Nantes-based biotech that develops “glyco-humanized” polyclonal antibodies. Its technological platform is built on dual expertise in 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, member of the Atlanpole Biotherapies competitiveness cluster, is part of the scientific and medical environment of Pays de la Loire. The company has since been supported by private investors, by the Pays de la Loire region, and by BPI France.

More information: www.xenothera.com

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