Press release
Nantes (France), October 25, 2023

#COVID #traitement #XAV19

Publication of clinical results for XAV-19, XENOTHERA's anti-COVID antibody -

French biotech announces its therapeutic potential for oxygen-free patients.

The French and European phase II and II/III clinical trials (Polycor and Euroxav) evaluating the therapeutic value of the anti-Covid XAV-19 treatment developed by Nantes-based biotech company XENOTHERA have delivered their conclusions. In all, data from 667 patients who took part in one of these trials were analyzed. Three conclusions were drawn. Firstly, the safety of XAV-19 in all patients. Secondly, a highly significant acceleration (p= 0.0003) of recovery in patients without oxygen. Finally, as other antibodies developed against COVID, a non-detectable benefit in patients requiring oxygen. The scientific paper is available here. XAV-19 is therefore a potential treatment for immunocompromised patients without oxygen, especially as its activity is maintained on SARS-CoV-2 variants.

With an average age of just under 60, the majority of patients volunteering for the XAV-19 trials had not been vaccinated, which can be explained by the main recruitment period for the two trials (in the year 2021 for the vast majority). In both trials, the male population was slightly over-represented (54% for Euroxav). The analyses carried out confirm two main risk factors for worsening COVID, namely age over 70 and comorbidities (body mass index, diabetes, cardiac or vascular pathology, hypercholesterolemia, renal insufficiency, chronic obstructive bronchitis and/or asthma).

Safety data show that the rate of adverse events (serious or not) was identical in patients receiving either XAV-19 or placebo. These analyses support the drug safety and confirm the value of XENOTHERA's technological approach (glyco-humanization of antibodies).

As far as efficacy is concerned, the benefit of XAV-19 is highly significant in patients without oxygen, whether hospitalized or at home, with a significant reduction of the time to recovery (median), which was reduced from 14 days to 7 days (p=0.0159) for all non-oxygen-requiring patients, and from 14 to 4 days for non-hospitalized patients (p=0.0003). Like other antibodies, especially monoclonals, XAV-19 did not bring detectable improvement to patients hospitalized on oxygen. At this stage, the administration of anti-virus antibodies no longer seems to be able to halt disease progression. The results are consistent in both trials, keeping in mind that Polycor targeted patients hospitalized on oxygen, whereas Euroxav recruited patients with varying degrees of disease severity, including non-hospitalized patients.

In the same scientific paper, the efficacy of XAV-19 on circulating variants is demonstrated, whereas monoclonal antibodies no longer work on these variants.

Taken together, these data underline the uniqueness of polyclonal antibodies such as XAV-19 in avoiding viral escape mechanisms, and their potential therapeutic interest for patients in need of antibodies (transplant patients, immunocompromised patients, or those unresponsive to vaccination) in the early stages of the disease.

"This could be the end of the story for our XAV-19 treatment. Having said that, it's a wonderful team story, a wonderful mobilization, and the support of all those who helped us, especially the patients and care teams, whom I'd like to thank once again. We could regret some errors, particularly in the design and analysis of these two trials, but that would be pointless. What happened is in the past. At XENOTHERA, we're proud of the fact that we did everything we could for patients, and that's our vocation. To date, we still have 30,000 doses ready for use, but the rules of the game when it comes to innovative drugs will unfortunately not allow us to give them away without carrying out another clinical trial, which we cannot afford to do. COVID is no longer a major cause for institutions, and this is good news per se, even if there are still patients for whom it is a serious issue. During this intense period, XENOTHERA will have progressed on many fronts, developing innovative antibodies in several therapeutic areas. We are now confirmed as a highly credible player in healthcare innovation, particularly in cancer, our priority battle to date.", comments **Odile Duvaux, President and co-founder of XENOTHERA.**

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About XAV-19:
XAV-19 treatment is a protective anti-SARS-CoV-2 polyclonal antibody similar to the natural human response. Based on a unique and patented proprietary polyclonal antibody production technology, it acts through multiple mechanisms of action, including virus neutralization and inflammation reduction, and is active on all circulating variants. The treatment is intended for patients with moderate Covid, to prevent the disease from worsening and progressing to the severe form, and thus avoid transfer to intensive care. In May 2021, the French government pre-ordered 30,000 injectable doses of this treatment.

About XENOTHERA:
Founded in 2014 by a team of renowned scientists (Prof. Jean-Paul Soulillou, Nantes, Prof. Jean-Marie Bach, Nantes, Prof. Emanuele Cozzi, Padua, Prof. Cesare Galli, Cremona) and under the presidency of Odile Duvaux, Doctor of Medicine and graduate of the École Normale Supérieure, XENOTHERA is a Nantes-based biotech company developing new therapeutic approaches in a wide range of fields, with a focus on oncology and immunology. The company develops treatments based on a unique glyco-humanized antibody technology. Its technological platform is based on dual expertise in genetics and immunology.
The biotech has a comprehensive portfolio of products, four of which are in clinic. Its main assets are LIS1, in onco-hematology and transplantation, and XON7, in solid tumors.
XENOTHERA is part of the scientific and medical environment of the Pays de la Loire region (France). Since its creation, the company has raised 43 million euros, its main financiers being the Pays de la Loire Region, BPI France and the European fund EIC Fund, as well as private investors.

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