Press information
Nantes (France), July 11th, 2022

#immunosuppressant #transplantation #LIS1

Orphan designation by the European Medicines Agency for LIS1, the transplant induction therapy from the pharmaceutical company XENOTHERA

Following the announcement of initial safety and efficacy results for its transplant immunosuppressant LIS1, XENOTHERA has been granted orphan drug designation by the European Medicines Agency (EMA).

The Committee for Orphan Medicinal Products (COMP) published on 27 June **its positive opinion for the orphan drug designation of LIS1** in the treatment of solid organ transplantation. This Committee of the European Medicines Agency is responsible for evaluating applications for orphan designation for medicinal products dedicated for the diagnosis, prevention or treatment of rare diseases (opinion available on the EMA website). The criteria for orphan designation are the severity of the disease, its prevalence, the absence of unprompted marketing, and a significant benefit for the patients to whom the medicine is to be administered.
Orphan drug designation had already been granted to LIS1 by the US Drug Administration (FDA) in 2020.

The orphan drug designation is a valuable support for the development of LIS1: tax incentive, technical assistance for the dossier, facilitation of administrative procedures, intellectual property protection and exclusivity after the obtention of the market authorization.

LIS1 is **a glyco-humanized polyclonal antibody and immunosuppressant for induction in solid organ transplantation**. This treatment, based on XENOTHERA's technology platform, is **designed to reduce the risk of acute rejection in the immediate post-transplant period**.

At the recent American Transplant Congress (ATC 2022, Boston, USA), Professor Ondrej Viklicky from the IKEM Institute - one of Europe's leading kidney transplant centers (Prague, Czech Republic) presented the data confirming **the potential of the drug**. XENOTHERA is preparing the next phase of LIS1 clinical development, with **a confirmatory trial (phase II/III) planned for 2023**, to be conducted in several transplant centers in Europe and the US.

"This orphan drug designation for LIS1 is a very good news for transplanted patients, first, to whom we hope to bring a significant therapeutic benefit. It is also a good news for XENOTHERA as orphan drug designation allows us to accelerate the development of LIS1, our original program. This regulatory step is an objective confirmation of the value of the product, a result of the scientific excellence at the Center for Research in Transplantation and Immunology (CRTI, Nantes, France)" comments **Odile Duvaux, CEO and co-founder of XENOTHERA**.

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About solid organ transplantation:
There are 130,000 solid organ transplants per year, including 36,000 are in the US and 23,000 in Europe, with an annual growth rate of 3%. The demand is constantly increasing, especially in emerging countries, notably China. The ageing of the population and the increase in chronic diseases are impacting the demand for transplants. In France, 12,500 people are on the waiting list. 50% of kidney transplants are rejected after 15 years, and this period is reduced to 8 years for lung transplants.

About LIS1:
LIS1 is one of the innovative immunotherapy approaches developed by XENOTHERA, based on technology from INSERM and the University of Nantes. This polyclonal depleting antibody is potentially aimed at the 130,000 people who receive solid organ transplants each year and at a market estimated at over one billion dollars. This new induction therapy for LIS1 transplantation is an intravenous solution administered immediately after transplantation.

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 to produce "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.
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