Press information
Nantes (France), September 12, 2023

New hope for patients: XENOTHERA granted orphan drug designation (ODD[1]) from the FDA for LIS1 in the treatment of T-lymphomas.

T-lymphomas are a heterogeneous group of serious diseases with an uncertain course, where new treatments are needed. LIS1, derived from the antibody technology platform (GH-pAb[2]) of the French biotech XENOTHERA, has proven its efficacy against T-lymphomas in preclinical studies. Based on XENOTHERA's scientific and medical data, the U.S. Food and Drug Administration (FDA) has just granted LIS1 orphan drug designation (ODD) for the treatment of T lymphomas.

XENOTHERA's R&D teams have demonstrated, in vitro and in vivo, the efficacy of LIS1 treatment on several T lymphomas. Given the heterogeneity of this disease, XENOTHERA's researchers have explored the potential of LIS1 on different subtypes and shown that up to 90% of patients' tumors are likely to be sensitive to LIS1. XENOTHERA's antibody thus represents a new therapeutic hope for T lymphoma patients, whose prognosis is particularly unfavorable.

Orphan drug designation is a major step, as formal confirmation by a regulatory agency; by its decision, the FDA affirms the therapeutic interest of a future drug for patients for whom no treatment is available. In addition to this external confirmation of the biotech's results and strategy, the ODD will enable XENOTHERA's LIS1 to benefit from free and accelerated regulatory processes, tax advantages and a 7-year marketing exclusivity once the market authorization is obtained.

"*Recognition of the quality and therapeutic value of a drug candidate is always an important milestone for a biotech. Here, the analysis of our data by the FDA confirms the soundness of our strategy in the field of cancer, onco-hematology for LIS1, and solid tumors for XON7. We are more than happy to bring new hope to T lymphoma patients, for whom the treatments available today are unfortunately of limited efficacy. LIS1 will be an additional weapon in the arsenal of treatments available to hematologists, who are keenly interested in innovative therapies such as XENOTHERA's. The first clinical trial in T-lymphoma is scheduled early 2024; this ODD confirms the importance of moving forward, for the good of patients, and we will put all our energy into making the treatment available to patients as quickly as possible*," comments **Odile Duvaux, President and co-founder of XENOTHERA**.

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About T lymphomas:
T lymphomas are a heterogeneous group of pathologies, divided into several categories: primary cutaneous, peripheral lymph node, leukemic and extra-lymph node. Depending on their molecular structure, they are classified into several sub-categories, all belonging to the "non-Hodgkin's lymphoma" class. Treatment approaches and prognosis vary according to subcategory. In the USA, they account for 15% of non-Hodgkin's lymphomas, or around 12,000 new cases per year. In France, they are estimated to account for around 1% of all cancers. Their course is generally aggressive[3].

[1] Orphan Drug Designation
[2] Glyco-Humanized Polyclonal Antibody
[3] Source: https://www.centreleonberard.fr/patient-proche/cancers-pris-en-charge/cancers-hematologiques/le-lymphome/le-lymphome-t

About LIS1:
LIS1 is a humanized polyclonal antibody (GH-pAb) from XENOTHERA's platform, in development since 2014, targeting lymphocyte antigens. It is presented as a solution for intravenous administration. LIS1 was introduced in human in 2019, with a first exploratory clinical trial in kidney transplant patients in Europe, completed in 2022. This trial confirmed the product's safety. LIS1 first indication is the prevention of acute rejection in solid organ transplantation, for which an ODD has already been granted by the FDA and EMA. T lymphomas represent a second indication for the product. The first LIS1 clinical trial in T lymphoma is scheduled early 2024.

About XENOTHERA:
Founded in 2014 by a team of renowned scientists (Prof. Jean-Paul Soulillou, Nantes, Prof. Jean-Marie Bach, Nantes, Prof. Emanuele Cozzi, Padova, Prof. Cesare Galli, Cremona) and under the presidency of Odile Duvaux, medical doctor, and graduate of the Ecole Normale Supérieure, XENOTHERA is a Nantes-based biotech company developing new therapeutic approaches in a wide range of fields, with a clear focus on oncology and immunology. The company develops treatments based on a unique proprietary technology of glyco-humanized antibody. Its technological platform is built on dual expertise in genetics and immunology.

The biotech has a full portfolio of products, three of which are in the 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 funders being the Pays de la Loire Region, BPI France and the European fund EIC Fund, as well as private investors.
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