

Lys Therapeutics announces a seed round of 5.5 million euros to prepare future clinical studies for its first-in-class monoclonal antibody targeting neurovascular and neurodegenerative disorders

A novel biotherapy targeting the blood-brain barrier dysfunctions to treat patients suffering from disabling neurological diseases

Lyon & Caen, France, 14 November 2022 – Lys Therapeutics, a French biotechnology company developing innovative therapies for neurovascular and neurodegenerative diseases, announced today its **first fundraising of 5.5 million euros**. This seed round of financing consists of 3 million euros in equity investment led by a consortium of qualified investors including **HTH VC**, and 2.5 million euros in grants, loans and repayable advances through **Bpifrance**, as well as other banking institutions.

Lys Therapeutics is a preclinical stage biotechnology company pioneering a revolutionary approach to treat neurological diseases through antagonism of the interaction between the tissue plasminogen activator (tPA) and the NMDA receptor (NMDAr) in blood vessels, leading to the restoration of physiological function of the NMDAr and of the blood-brain barrier (BBB), and associated neuroinflammatory processes. Lys Therapeutics was incorporated in March 2021, is a French Tech Seed-labeled company and was a winner of the prestigious i-Lab Innovation Competition (Grand Prize of the jury) in 2021. In order to intensify its research projects, the company has signed collaborations with internationally renowned academic teams in Europe, the United Kingdom and the United States.

This financing will allow Lys Therapeutics to produce the monoclonal antibody Glunozumab® for which the company holds the exclusive worldwide patent rights, in accordance with Good Manufacturing Practice (GMP), and to complete its regulatory preclinical studies in order to support its future clinical trials planned to start in the second half of 2024. The targeted indications are neurovascular diseases, in particular ischemic stroke, as well as neurodegenerative diseases, such as multiple sclerosis and Parkinson's disease.

HTH VC (Health Technology Holding, the investment fund of Zambon pharmaceutical company) and Philippe Bissay, CEO of the pharmaceutical company H.A.C. Pharma, support the development of Lys Therapeutics and express their confidence in the research carried out by the company based on the initial work from Inserm and the University of Caen-Normandie through the Blood and Brain Institute (Blood and Brain @ Caen-Normandie Institute) and the joint research unit UMR-S 1237 PhIND (Physiopathology and Imaging of Neurological Disorders) headed by Professor Denis Vivien.

“The milestones already achieved by Lys Therapeutics since its creation truly impressed us. We have been particularly convinced by the quality of the team and the science behind the company. The groundbreaking mechanism of action of Glunozumab® can tackle many fields of application. The fact that the antibody does not need to cross the blood-brain barrier is a very distinctive and extremely innovative element for the treatment of neurological diseases. This fundraising will allow Lys Therapeutics to accelerate its GMP production and launch its regulatory studies with the purpose to treat several neurological pathologies with high unmet medical needs,” says Michele Gaiotto, CEO of HTH.

"The demonstrations of the scientific validity of the mechanism of action of the drug candidate as well as the experience of Lys Therapeutics' team are real success factors for the project. The NMDA receptor and its overactivation by endogenous tPA is a major mechanism in the pathophysiology of many neurological diseases; restoring its physiological function, as the monoclonal antibody Glunozumab® does, is an extremely promising avenue for combating the progression of these disabling pathologies." says Philippe Bissay, CEO of H.A.C. Pharma, investor and member of the strategic advisory board of Lys Therapeutics.

"We are confident in the development work carried out by Lys Therapeutics, and in the strong potential of this antibody, supported by Bpifrance since the company's creation, notably with the French Tech Emergence grant and the i-Lab innovation competition. We are particularly proud to renew our support and to contribute to the acceleration of this project and its breakthrough innovation to treat patients suffering from severe neurological diseases" states Florent Lepert, Regional Director of Bpifrance.

"I would like to thank our financial partners who trust us to carry out this ambitious project. We want to significantly improve the treatment of patients suffering from neurological diseases related to blood-brain barrier dysfunctions such as neurovascular or neurodegenerative disorders. To achieve this, we have assembled a strong and complementary team of drug development experts, international researchers, clinicians and key opinion leaders, as well as qualified investors" says Manuel Blanc, President and co-founder of Lys Therapeutics. "The company is perfectly positioned to deploy its innovative preclinical programs, for which a strong scientific interest is demonstrated by ongoing discussions with several international pharmaceutical companies and world-renown academic teams. With this financing, Lys Therapeutics has the necessary resources to achieve its next research and development objectives in order to prepare the future clinical trials of its first-in-class drug candidate Glunozumab®".

A unique mechanism of action to protect the blood-brain barrier.

In the pathophysiology of many neurological diseases such as stroke, multiple sclerosis, Parkinson's disease and other neurodegenerative diseases, the tPA, an endogenous protease, is overexpressed leading to deleterious hyperactivation of vascular NMDAr, causing an abnormal permeabilization and even a rupture of the BBB and transmigration of inflammatory cells into the brain. Glunozumab® specifically blocks the interaction between tPA and the NMDA receptor, thereby eliminating the harmful effects of this binding: neurotoxicity, neuroinflammation and disruption of the BBB, while restoring the physiological function of the NMDAr. This unique mechanism of action means that Glunozumab® does not need to cross the BBB to act in the central nervous system, which is a particularly distinctive feature for the treatment of neurological diseases.

Neurovascular diseases: the first cause of death in women.

Among neurovascular diseases, stroke is the most common pathology with the strongest social and economic impact. Stroke is characterized by a sudden stop of blood circulation in the brain, causing severe damage to neural cells, and can lead to partial paralysis or death of the patient. Every year in France, more than 150,000 people suffer a stroke, more than 110,000 are hospitalized and 30,000 die. Currently, more than 500,000 French people live with permanent after-effects (source: French Ministry of Health).

A few figures illustrate the prevalence of stroke in the world:

- More than 17 million cases each year, 31% of which occur in people under 65 years of age resulting in 6 million deaths annually
- the second leading cause of death for all diseases combined (source : WHO) and the leading cause of death for women
- the second cause of dementia and the first cause of acquired disability in adults (source Inserm)

Neurodegenerative diseases: on the rise with aging.

Due to the progressive aging of the population and the lack of curative treatments, the number of people suffering from neurodegenerative diseases has increased considerably over the last decades and is expected to grow steadily in the coming years. Worldwide, 50 million people are affected by neurodegenerative diseases according to the WHO, and this number will double by 2050.

In France, more than one million people are affected by Alzheimer's disease and approximately 160,000 people are treated for Parkinson's disease, according to French Public Health authorities.

Multiple sclerosis affects more than 110,000 people in France, more than 1 million in Europe and 2.8 million worldwide. In 70% of cases, the disease begins between the ages of 25 and 35 and, among those affected, 3 out of 4 are women.

About HTH VC

HTH is a Venture Capital investment company investing alongside bright innovators dedicated to improve humans' health. Born in 2020, HTH complements ZCube-Zambon Research Venture scouting and investing activities with direct participation in early stage deep tech start-ups dedicated to improve human lives.

About Bpifrance

Bpifrance finances companies - at every stage of their development - with credit, guarantees and equity. Bpifrance supports them in their innovation and international projects. Bpifrance also ensures their export activity through a wide range of products. Advice, university, networking and acceleration programs for start-ups, SMEs and ETIs are also part of the offer to entrepreneurs. Thanks to Bpifrance and its 50 regional offices, entrepreneurs benefit from a close, single and efficient contact to help them face their challenges.

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About Lys Therapeutics

Lys Therapeutics is a biotechnology company pioneering a breakthrough approach to treat patients suffering from neurovascular or neurodegenerative disorders, including ischemic stroke as well as multiple sclerosis. Its main drug is a first-in-class monoclonal antibody, **Glunozumab®**, displaying an exclusive and groundbreaking mechanism of action linked to blood-brain barrier dysfunctions.

Targeting major societal impact, the clinical development of Glunozumab® biotherapy is of priority for Lys Therapeutics, as a potential game changer for patients suffering from neurological disorders with high unmet medical needs.

Find out more: lystherapeutics.com

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