

Nine startups are working on brain pathologies together with the Blood and Brain Institute BB@C in Normandy

Worldwide Brain Awareness Week from March 14 to 20, 2022

Neurovascular diseases, neurodegenerative disorders, and mental health: research and treatments are progressing in Caen.

Caen, France, March 14, 2022 – Lys Therapeutics, a French biotech company developing innovative drugs to treat patients suffering from neurovascular or neurodegenerative disorders along with the Blood and Brain @ Caen-Normandie Institute (BB@C) and eight partnered startups are joining forces on the occasion of Worldwide Brain Awareness Week as they share the same mission: provide medical solutions for pathologies affecting the brain.



Celebrated annually in the third week March, Brain Awareness Week is an international event coordinated in France by “La Société des Neurosciences”. Organized in one hundred countries and more than 120 cities in France, its goal is to raise public awareness about brain research. It is an opportunity for many researchers to meet the public, share research progress and raise awareness about both health and social issues related to these diseases.

Neurological pathologies at the heart of medical needs

The many diseases that affect nerve cells vary in their mode of expression, are only partially understood, and for some may be associated with aging. In France, one person out of three is affected - directly or indirectly - by a neurovascular disease, a neurodegenerative disease or mental disorders.

Neurovascular diseases: first cause of death among women

Among neurovascular diseases, stroke is the most common pathology with the biggest social and economic impact. Stroke occurs when the blood supply to part of the brain is interrupted or reduced, causing severe damage to cells and leading to partial paralysis or death. 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).

Worldwide, strokes also represent:

- more than 17 million cases each year, 31% of which occur in people under the age of 65, for 6 million deaths annually,
- the second leading cause of death, for all diseases considered (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).

Mental health: a large-scale problem

According to the WHO, 450 million people are suffering from mental or behavioral disorders worldwide. In one family out of four, at least one person suffers from a mental disorder. Psychiatric and behavioral disorders include depression, bipolar affective disorder, schizophrenia and other psychoses, dementia, intellectual disability and developmental disorders, including autism.

Neurodegenerative diseases: increasing with an aging population

Due to an aging population and the lack of curative treatments, the number of people suffering from neurodegenerative diseases has increased considerably over recent 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 the French public health organization "Santé Publique France".

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

BB@C: a research institute for new therapeutic perspectives

The BB@C Institute ("Blood & Brain @ Caen Normandie Institute") is a scientific cooperative recognized both in France and internationally for its translational approach to neurovascular, neurodegenerative and psychiatric diseases. The institute regroups 9 start-ups, 4 academic laboratories and 3 cutting-edge technological platforms.

The nine start-ups:

- **Lys Therapeutics** is a French biotech company developing innovative drugs to treat patients suffering from neurovascular or neurodegenerative disorders, including stroke and multiple sclerosis. Its main drug is a first-in-class monoclonal antibody with an exclusive and groundbreaking mechanism of action.
- **Op2Lysis** is a French and Belgian biotechnology company dedicated to the development of breakthrough thrombolytic agents based on the NANOp2Lysis™ technology that improves their efficacy and their safety to treat life-threatening neurovascular diseases, in particular hemorrhagic stroke.
- **Neurallys** is developing a groundbreaking solution for hydrocephalus management to improve patient comfort, improve the therapeutic approach and develop a personalized medicine.
- **Robocath** is a company that designs, develops and markets innovative robotic solutions for the treatment of cardiovascular diseases.
- **Samdoc Medical Technologies** aims to revolutionize health monitoring and patient care by designing innovative digital solutions for remote medical analysis of body movements
- **Forlabs** works in the e-health sector with the goal of maximizing the value of each future software product.
- **Moment Tech** is a company specializing in artificial intelligence software.
- **Cynbiose** is a French preclinical CRO with over a decade of experience in the field of the Central Nervous System and has developed extensive expertise in exploratory pharmaco-toxicology studies as well as in predictive models for proof of concept (PoC)

- **ETAP-Lab** is a preclinical Contrat Research Organization (CRO) specialized in the fields of dermatology and neurology. ETAP-Lab co-founded STROK@LLIANCE, a CRO dedicated to preclinical stroke research.

Four academic labs:

- **PHIND**, UMR-S U1237: Inserm unit University of Caen, directed by Prof Denis Vivien (2 teams Pr D. Vivien/Dr M. Gauberti and Dr G. Chételat/Dr G. Rauchs).
- **Dr M. Merlini's Junior Research Group**: Neurovascular mechanisms of psychiatric symptoms and cognitive deficits in neurodegenerative and psychiatric diseases.
- **CERMN**, EA 4258 : Centre d'Etudes et de Recherches sur le Médicament de Normandie Institut Carnot, Groupe NanoXe, Dr E. Dubost.

Three technological platforms:

- **ESRP**: Experimental Stroke Research Platform, IBISA, Cyrille Orset, Benoit Haelewyn, Denis Vivien.
- **CYCERON BIOMEDICAL IMAGING**: Preclinical and clinical in vivo imaging, Benoît Haelewyn.
- **CRB-InnovaBIO**: Biological Resource Center, Denis Vivien.

Acting as one to provide better care for neurological pathologies

"The BB@C institute was designed to bring together startups, CROs, academic pre-clinical and clinical research teams, and technological platforms, in order to create a united structure for neuroscience research," enthusiastically explains Professor Denis VIVIEN, Scientific Director of the Blood and Brain Institute @ Caen-Normandie (BB@C, GIS Inserm / University of Caen-Normandie and CHU of Caen-Normandie), " Science is making huge progress, the researchers and startups of BB@C are reinventing themselves every day to find solutions for better diagnoses and better treatments for these brain diseases. This is our daily motivation."

"Providing better care for patients suffering from neurological diseases is a priority in France and around the world. While these diseases are on the rise, therapeutic solutions remain unfortunately very limited. Lys Therapeutics, like its eight BB@C partner startups, is dedicated to meet these unmet medical needs," explains Dr. Manuel Blanc, President and co-founder of Lys Therapeutics, who adds, "The research conducted at Lys Therapeutics shows that there are areas for improvement for patients suffering from neurovascular or neurodegenerative diseases. So it is very important for us to support the global initiative to raise awareness about the societal impact that neurological pathologies represent as a whole."

"Op2Lysis was created with the objective of providing the first medical treatment for patients with hemorrhagic stroke, an unmet medical need, based on academic research conducted with Prof. Vivien's unit. The NANOp2LysisTM technology, currently developed by the company, opens the door to a portfolio of treatments for neurovascular diseases. The research and development activities of the start-ups and the academic research structures are complementary and carry day after day the hope of improving patient care and ensuring healthier ageing" says Dr. Jérôme Parcq, co-founder and CEO of Op2Lysis.

"Neurallys is very focused on neurosciences, targeting patient comfort improvement and the design of modern solutions for neurosurgery, more specifically on a pathology with very little evolution over the past 60 years" explains Philippe Auvray, CEO of Neurallys, who adds "In addition to the technology which drives the revolution of medical areas, such as the hydrocephalus we are focusing on, the research environment we need has to be best-in-class to address the multiples aspects of high-tech medical devices development. This is exactly what we found within the BB@C institute".

"At ETAP-Lab, our mission is to support and guide the development of new therapeutic strategies," says Dr Nicolas Violle (CEO). "We are pooling our resources with those of the ESRP platform, the PhIND team and CYCERON – and as a result, ETAP-Lab is now in a position to provide R&D in the field of stroke. Our STROK@LLIANCE brand offers preclinical studies designed to predict the efficacy of molecules coming from the pharmaceutical and biotech industries, and this exciting – yet challenging – work represents our one-of-a-kind contribution to the development of future therapies for stroke."

"Robocath was founded nearly ten years ago with the ambition of improving patient care for serious vascular accidents such as stroke by developing robotic solutions capable of intervening remotely with extreme precision and in a reduced timeframe. Indeed, guaranteeing equal access to care across the country is fundamental today, and robotics is undoubtedly a response to this major societal challenge. It will enable us to ensure that patients have rapid access to the best treatment by the best practitioners in this field, who will operate from an expert center to peripheral emergency reception centers. I would like to thank the partner companies for their investment and dedication to the treatment of brain pathologies including stroke, the second leading cause of death worldwide." says Dr. Philippe Bencteux, co-founder and CEO of Robocath.

"Increasing research visibility and its understanding by all is a fundamental aspect of our mission, especially for patients with neurological diseases and their families. Also, because the fields of application that aim to improve therapeutic solutions are more and more numerous, it is our mission to keep the public up to date with these progresses. I am particularly delighted that French start-ups, notably based in Caen, are emerging and can bear the fruit of this research." declares Dr. Olivier Dufor, volunteer for the French organization of the Brain Awareness Week ("La Semaine du Cerveau") in Caen.

About BB@C Institute

The Blood and Brain @ Caen-Normandy Institute (BB@C), founded by Inserm, the University of Caen-Normandy and the Caen-Normandy University Hospital, supported by the Normandy Region as well as private foundations, is internationally recognized for the excellence of its biomedical and translational research activities. BB@C brings together scientists of different horizons. Collectively, the teams at BB@C share four main goals: 1) Improving research in neurovascular, neurological and psychiatric disorders, particularly involving blood-brain interactions, 2) Obtaining a high level of expertise and knowledge in these fields, 3) Promoting innovations and partnerships to the benefit of patients, 4) Bringing science and the general public closer together in a climate of mutual confidence. The different structures constituting BB@C (institutions, laboratories, technology platforms, start-ups and CROs.) combine complementary skills and expertise in a translational science approach for a common purpose: advancing research on neurovascular, neurological and psychiatric disorders in order to improve patient care. www.bb-c.fr

About Op2lysis

Op2Lysis is a French and Belgian biotechnology company dedicated to the development of next-generation thrombolytic agents based on a breakthrough technology, NANOp2LysisTM, improving their efficacy and safety to treat life-threatening neurovascular diseases. With its first drug, O2L-001, Op2Lysis is dedicated to developing the first medical treatment for hemorrhagic stroke, the most severe form of stroke. O2L-001 is a locally administered treatment designed to liquefy the intracerebral hematoma that has formed following a hemorrhagic stroke, so that the blood can be easily removed by a minimally invasive surgical technique and the hematoma reduced in size.

The company's strategy is to develop high added-value therapeutic solutions for conditions where the clinical proof of concept of the therapeutic strategy has already been demonstrated in order to increase the chances of success of its drug candidates. For hemorrhagic stroke, a clinical proof of concept supports O2L-001, with a strong association between blood volume reduction and clinical benefit resulting in fewer deaths and disabilities. The competitive advantages of O2L-001 observed in

the best translational models indicate a very high potential for efficacy and increased safety in this therapeutic indication.

The company aspires to expand its product portfolio, particularly in primary and secondary cerebral thrombosis, which are life-threatening or represent unmet medical needs. www.op2lysis.com

About Neurallys

Neurallys is developing a connected ambulatory medical device to monitor the intracranial pressure for patient suffering from high intracranial pressure (hydrocephalus) to improve patient comfort and provide neurosurgeons real world data, improving the patient follow-up and reducing the number of visit at hospital in case of patient symptoms.

Neurallys is an innovative neurosurgery company working on a pathology, hydrocephalus, which causes intracranial hypertension. It affects children from an early age, adults following severe head trauma, stroke or brain tumors and also 1% of seniors. In France, there are no less than 120,000 patients. The main treatment consists of implanting a "shunt", a device that drains cerebrospinal fluid from the brain to the abdomen to regulate intracranial pressure. It has a high rate of malfunction, which degrades patients' living conditions and requires numerous hospitalizations and revision surgeries. The device developed by Neurallys (small connected implant) will allow to measure the intracranial pressure and a Smartphone application will allow patients to enter information and enrich the clinical context. This data will allow neurosurgeons to determine the best therapeutic choices and eventually the need to come to the hospital.

Neurallys' ambition is to revolutionize this neurological field by also addressing the therapeutic aspect with a new-generation valve to truly revolutionize this therapeutic area. www.neurallys.com

About ETAP-lab

ETAP-Lab is a leading preclinical CRO, offering research services in the fields of Dermatology and Neurology aimed at evaluating drug and medical device efficacy. Since it was founded in 1991, ETAP-Lab has been working with numerous companies worldwide, from small biotechs to top 10 pharmaceutical companies, with a track record of success. The high-level scientific team analyses clients' needs, offers advice and works alongside them to draw up the solution best suited to testing their drugs and/or medical devices. ETAP-Lab performs studies to the highest industrial quality standards, ensuring reproducibility, transparency, traceability, confidentiality and responsiveness. In 2017, ETAP-lab created STROK@LLIANCE in partnership with the University of Caen Normandy and the highly-regarded PHIND laboratory (UMR1237, INSERM, UNICAEN). STROK@LLIANCE also benefits from the medical imagery facilities and support of CYCERON. STROK@LLIANCE provides its clients with the opportunity to work with a unit that is fully dedicated to preclinical stroke in order to address their questions on stroke mechanisms, diagnostics and therapeutics. STROK@LLIANCE offers the best from public and private preclinical research in a unique service, providing scientifically sound protocols and advice, cutting-edge technologies and methodologies, and quality-controlled studies in a fast-paced result-oriented environment. www.etap-lab.com & www.strokalliance.com

About Robocath

Founded in 2009 by Philippe Bencteux, MD, Robocath designs, develops and commercializes robotic solutions to treat cardiovascular diseases. As an active player in the evolving medical robotics industry, these innovative solutions aim to make medical procedures safer thanks to reliable technologies, while complementing manual interventions.

R-One™ is the first solution developed by Robocath. It uses a unique bionic technology that optimizes the safety of robotic-assisted coronary angioplasty. This medical procedure consists of revascularizing the cardiac muscle by inserting one or more implants (stents) into the arteries that supply it with blood. Every 30 seconds, somewhere in the world, this type of procedure is performed. R-One is designed to operate with precision and perform specific movements, creating better interventional conditions. Thanks to its open architecture, R-One is compatible with market-leading devices and cath labs.

Robocath aims to become the world leader in vascular robotics and develop the remote treatment of vascular emergencies, guaranteeing the best care pathway for all. Based in Rouen, France, Robocath has more than 60 employees.

www.robocath.com

About Lys Therapeutics

Lys Therapeutics is a biotechnology company pioneering a breakthrough approach to treat patients suffering from neurodegenerative or neurovascular disorders. Its main drug is a first-in-class monoclonal antibody displaying an exclusive and groundbreaking mechanism of action.

It is demonstrated that one endogenous protease called tissue plasminogen activator (tPA) is implicated in the **pathophysiology** of neurological diseases such as **multiple sclerosis, Parkinson's disease, stroke** and other **neurodegenerative disorders** through its overexpression and binding to NMDA receptors (NMDAr) present on vascular endothelial cells and regulating the blood brain barrier (BBB) function / dysfunction. The overactivation of vascular NMDAr is triggering a strong increase of the permeability of the BBB allowing **the transmigration of toxic immune cells to the brain parenchyma** leading to neuroinflammation, ultimately causing neurodegeneration.

By blocking the tPA-NMDAr interaction inside the blood vessels, Lys Therapeutics drug candidate is restoring both NMDAr and blood-brain barrier physiological functioning (**no perturbation of basal function**), **blocking both neuroinflammatory and neurodegenerative processes**.

This unique mechanism of action implies that **it does not need to cross the BBB to act on the central nervous system**, which is a distinctive feature for the treatment of neurological diseases.

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

More information on lystherapeutics.com

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