

Press Release

First Patients Enrolled in the CoviTREM-1 Program



October 7, 2020 – Today, the CoviTREM-1 consortium, regrouping Nancy and Limoges teaching hospitals with Inotrem, announces that it has enrolled its first patients. CoviTREM-1 is funded as part of the call for proposals PSPC-COVID, managed on behalf of the Government by Bpifrance as part of the “Investissements d’Avenir” Program and supervised by the “ Secrétariat général pour l’investissement”. This program is meant to support collaborative research and development efforts to bring new therapeutic solutions targeting COVID-19.

CoviTREM-1: a program that targets the TREM-1 pathway in COVID-19

Among the six projects selected in this call for proposals, the CoviTREM-1 program aims at evaluating the safety and efficacy of nangibotide in COVID-19 patients with a severe form of the disease in a sixty patients strong phase 2a clinical trial, as well as characterizing the evolution of TREM-1 expression during the course of the disease in a prospective cohort of up to 1 000 hospitalized patients. Inotrem led the efforts to gain approval for the evaluation of nangibotide in COVID-19 patients whereas Nancy Hospital clinical development teams were instrumental in setting up the cohort. Pr. Sébastien Gibot, from the Nancy Hospital, is the coordinating investigator for both studies.

The development of nangibotide, a novel immunomodulator

TREM-1 is an immunomodulatory receptor expressed on innate immune cells, which amplifies and maintains inflammation. Nangibotide is a first-in-class TREM-1 inhibitor that has already demonstrated preliminary safety and efficacy results in its first indication (septic shock). Inotrem is currently conducting a phase 2b trial (ASTONISH) with nangibotide to treat septic shock patients in six European countries and in the United States.

A first concrete step completed in a record fashion

For the phase 2a in COVID-19 under the CoviTREM-1 program, the first subject was randomized and dosed at the Limoges Hospital on 22nd September 2020, only one week after the site initiation. After the Nancy University Regional Hospital obtained the approval from the regulatory authorities in a record time (one month only), the first patient was also enrolled into the cohort on 22nd September, in the Emergency Department of the Limoges Hospital.

This demonstrates the capacity of both institutions to set up these two challenging trials in a short time period. A lot of efforts have gone into shortening the timelines and the enrolment of the first patients in both studies represents a major milestone for the CoviTREM-1 program. It demonstrates clearly how fruitful an effective collaboration between the academics and the private partners can be.



“This first patients’ enrollment is an important stepstone that we are proud to share. Our long-standing collaboration with the hospitals of Limoges and Nancy perfectly illustrates how industrial and institutional partners can efficiently work together to bring new therapeutic solutions to patients who, apart from supportive therapies, do not have access to any satisfying causal treatment.”

Jean-Jacques GARAUD

Inotrem

CEO

“We were the first to observe that the TREM-1 pathway is activated in severe forms of COVID-19 and we are keen to learn more about the implication of this pathway in the evolution of COVID-19. We are also hoping to demonstrate that nangibotide will reduce the duration of hospitalization and mortality of critically ill patients suffering from COVID-19.”

Sébastien GIBOT

Nancy University Regional Hospital

Coordinating Investigator

Head, Medical Intensive Care Unit

About Inotrem

Inotrem S.A. is a biotechnology company specialized in immunotherapy for acute and chronic inflammatory syndromes. The company has developed a new concept of immunomodulation that targets the TREM-1 pathway to control unbalanced inflammatory responses. Through its proprietary technology platform, Inotrem has developed the first-in-class TREM-1 inhibitor, LR12 (nangibotide), with potential applications in a number of therapeutic indications such as septic shock. In parallel, Inotrem has also launched another program to develop a new therapeutic modality targeting chronic inflammatory diseases. The company was founded in 2013 by Dr. Jean-Jacques Garaud, a former head of research and early development at the Roche Group, Prof. Sébastien Gibot and Dr. Marc Derive. Inotrem is supported by leading European and North American investors. Inotrem belongs to the French Tech 120 program which has been set up by the French President and the Prime Minister to support the development of start-ups with top growth potential.

www.inotrem.com

About TREM-1 pathway

TREM-1 pathway is an amplification loop of the immune response that triggers an exuberant and hyperactivated immune state which is known to play a crucial role in the pathophysiology of septic shock and acute myocardial infarction.

About nangibotide

Nangibotide is the formulation of the active ingredient LR12, which is a 12 amino-acid peptide prepared by chemical synthesis. LR12 is a specific TREM-1 inhibitor, acting as a decoy receptor and interfering in the binding of TREM-1 and its ligand. In preclinical septic shock models, nangibotide was able to restore appropriate inflammatory response, vascular function, and improved animals’ survival post septic shock.

About ASTONISH Study

The Efficacy, Safety and Tolerability of nangibotide in Patients with Septic Shock (ASTONISH) phase 2b trial is a Randomized, Double-blind, Placebo Controlled Dose Selection Study that will be performed Europe and the US. Four hundred and fifty patients are planned to be included in this study in 48 clinical sites. The study will compare the effect of nangibotide at two different doses versus standard of care.

About Limoges Hospital

Centre Hospitalier Universitaire de Limoges was created in 1976 with three main missions: patient care, teaching and research & innovation. CHUL is made up of 5 different hospitals with more than 7,000 professionals and one Inserm-certified Clinical Investigational Center (CIC 1435) which gathers almost 50 people (physicians, European project managers, study nurses, clinical research assistants, financial officers, medical translators, etc.). The CIC 1435 is dedicated to the promotion and implementation of clinical research within and outside the Limoges Hospital. A unique large Medical-Surgical ICU of 22 beds works closely with the CIC and has a specific expertise in emergency trials, being often the highest enroller in multicenter international Sepsis trials.

www.chu-limoges.fr



About Nancy Hospital

A public healthcare centre with 9,000 professionals, the Centre Régional Hospitalier Universitaire de Nancy (CHRU Nancy) carries out healthcare missions, thanks to its high-quality multidisciplinary medical expertise serving patients at all stages of life. Adult and pediatric emergencies, oncology, neurology, gynecology and obstetrics, cardiology, geriatrics, internal medicine, digestive surgery. With more than 40 medical and surgical specialties, the CHRU Nancy takes care 700,000 patients each year for 480,000 consultations, 136,000 hospitalizations (half of which are outpatient), 80,000 emergency visits and 3,300 births. Today, thanks to the deployment of its research structures (Biological Resource Centre, Clinical Investigation Center, Sponsoring, Vigilance, Investigation, Methodology Data management and Statistics) the CHRU Nancy occupies the 10th place in France in terms of research, a well-deserved position.

<http://www.chu-nancy.fr/>

About Bpifrance

Bpifrance is the French national bank for investment: it finances businesses – at every stage of their development – through loans, guarantees, equity investments and export insurances. Bpifrance also provides extra-financial services (training, consultancy) to help entrepreneurs meet their challenges (innovation, export...). Thanks to Bpifrance and its 50 regional offices, entrepreneurs benefit from a close, unique and effective contact to support them in facing their challenges.

For more information, please visit: www.bpifrance.fr/presse.bpifrance.fr

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About the Investments for the Future Program (*Programme d'investissements d'avenir*)

Endowed with 57 billion euros, the Investments for the Future Program, led by the General Secretariat for Investment (SGPI), was set up by the French government to finance innovative and promising investments in the territory, in order to allow France to increase its potential for growth and jobs. Since the launch of the Program, France has thus co-financed several thousand projects to prepare for the future.

More information on the SGPI website - Follow us on Twitter: @SGPI_avenir

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