



## Press Release

### **CoviTREM-1 consortium, composed of Inotrem, Nancy and Limoges teaching hospitals, announces it has completed patients' inclusion for its COVID-19 Phase IIa clinical study**



**Paris, Limoges, Nancy (France). February 3<sup>rd</sup>, 2021** – Today, the CoviTREM-1 consortium, regrouping Nancy and Limoges teaching hospitals with Inotrem, a biotechnology company specializing in immunotherapy for acute inflammatory syndromes, announces that it has completed the patients' inclusion of its Phase IIa clinical study with a total of 60 patients with severe forms of COVID-19. This COVID-19 trial, conducted by CoviTREM-1 consortium, is funded through the call for proposals PSPC COVID-19, managed by Bpifrance, France's public investment bank, as part of the "French Strategic Investment Program" (PIA). This call for proposals is meant to support collaborative research and development efforts to bring new therapeutic solutions targeting COVID-19. This Phase IIa clinical study has been declared "National Priority Research" by the French government steering committee for therapeutic clinical trials and other research (CAPNET) in December 2020. Results are expected for Q2 2021.

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

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 IIa 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.

#### **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 IIb trial (ASTONISH) with nangibotide to treat septic shock patients in six European countries and in the United States.

#### **A significant milestone**

For the phase IIa in COVID-19 under the CoviTREM-1 program, the first subject was randomized on September 22<sup>nd</sup>. 2020 and the 60<sup>th</sup> patient was randomized on January 27<sup>th</sup>. 2021. Five clinical centers in France (including Nancy and Limoges) and two in Belgium actively contributed to the inclusions.

*"Completing the inclusions in our phase IIa is an important stepstone that we are proud to share with all the investigators involved in the study. It is a real challenge to conduct a clinical study while managing an increasing flow of COVID-19 patients. We believe this is a daunting but necessary task if we are to bring to patients a new therapeutic solution such as nangibotide. I am truly grateful for the commitment showed by all centers involved in the study."*

**Jean-Jacques GARAUD**

Inotrem  
CEO



### **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](http://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, Inotrem's lead product candidate, 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 Inotrem's ASTONISH Study**

The Efficacy, Safety and Tolerability of nangibotide in Patients with Septic Shock (ASTONISH) phase IIb trial, conducted by Inotrem, is a Randomized, Double-blind, Placebo Controlled Dose Selection Study that is performed in 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](http://www.chu-limoges.fr)

### **About Nancy Hospital**

A public healthcare centre with 9,000 professionals, the Centre Regional 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 10<sup>th</sup> 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](http://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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