Inotrem announces Data Monitoring Committee (DMC) recommends continuation of Phase IIa study of nangibotide for the treatment of severe forms of COVID-19

Paris, December 21. 2020. Inotrem S.A., a biotechnology company specialized in the development of immunotherapies targeting the TREM-1 pathway, announces today that an independent Data Monitoring Committee (DMC) recommends continuation of the Phase IIa study of nangibotide for the treatment of severe forms of COVID-19 hospitalized in intensive care units (ICU). The DMC was composed of unblinded external medical experts and based its decision on a pre-planned interim analysis of safety. This positive decision will allow Inotrem and its partners, the CHRU of Nancy and the CHU of Limoges, to carry on without modification its Phase IIa trial.

The first interim analysis was based on the first 20 patients enrolled. Inotrem expects to complete patients' enrollment in France, Belgium, and the United States no later than the end the first quarter of 2021. The goal of this study is to determine the safety, tolerability and potential signals of efficacy of nangibotide in critically ill patients with COVID-19. Nangibotide is expected to have a positive impact on the severity of the respiratory failure, reduce duration of mechanical ventilation, length of stay in ICU and reduce mortality.

This study follows an observational study in 27 patients, conducted by Prof. Sébastien Gibot at the CHRU of Nancy, which reported an increased expression of the TREM-1 pathway in severe COVID-19 patients. TREM-1 is an immunomodulatory receptor expressed on innate immune cells which amplifies and maintains inflammation.

In parallel, Inotrem is also currently conducting a Phase IIb trial (ASTONISH) to treat septic shock patients with nangibotide in six European countries and in the United States. Previous clinical studies with nangibotide in septic shock demonstrated that it was safe, well tolerated and showed signals towards clinically relevant efficacy. Pre-clinical models have shown that nangibotide modulates the amplification of the immune response caused by the activation of TREM-1 and is able to restore appropriate inflammatory response and vascular function, resulting in improved survival in septic shock models.

To conduct the Phase IIa COVID-19 trial, Inotrem and its partners received a non-dilutive funding by the Investments d'Avenir Program which is managed on behalf of the French government by Bpifrance, France's public investment bank.

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 and myocardial infarction. 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.
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.

Media contact for Inotrem
Anne REIN
Strategies & Image (S&I)
anne.rein@strategiesimage.com
+33 6 03 35 92 05