

## **Inotrem announces positive results from the Phase IIa study of its lead compound, nangibotide (LR12), in the treatment of septic shock.**

- *The study demonstrated the safety and tolerability of its lead compound in patients suffering from septic shock*

**Paris, October 1<sup>st</sup>. 2018.** Inotrem S.A., a biotechnology focused on the modulation of the TREM pathway for the management of inflammatory syndromes, announced positive results for its Phase IIa study that demonstrated the safety and tolerability of its lead product candidate, nangibotide (LR12), in septic shock patients. The results were presented today at the annual congress of the International Sepsis Forum in Bangkok.

Septic shock is the ultimate complication of sepsis and currently constitutes an unmet medical need. The incidence of septic shock continuously raises and mortality remains elevated (35%) in developed countries. There is currently no specific therapy approved for this indication besides antibiotics and symptomatic agents, and Inotrem's solution has the potential to become the first mechanism-based treatment for septic shock. Nangibotide is developed by Inotrem and is based on a novel approach of immunomodulation: it specifically targets the TREM-1 pathway which is crucial mediator of the septic shock.

The reported study was an 11-months multicenter phase IIa clinical trial with 49 patients suffering from septic shock enrolled in four European countries (Belgium, France, The Netherlands and Spain). The results bring positive data on the safety and tolerability of Inotrem's lead product candidate, nangibotide, in septic shock patients. The study also showed that nangibotide treatment provided consistent trends in a more favorable evolution of biological and clinical activity markers in the subgroup of patients with soluble TREM-1 levels above median at entry. These results support Inotrem's personalized medicine approach: using soluble TREM-1 level in blood as a potential biomarker for the identification of patients who will most likely benefit from nangibotide treatment. The results from this clinical trial reinforce previous preclinical and clinical findings, in particular about the safety, biological and clinical activity of nangibotide and the use of sTREM-1 as a companion biomarker for patient selection. Consequently, the company intends to launch in 2019 a Phase IIb study, with the aim to bring a strong proof of clinical activity of nangibotide in septic shock patients.

Jean-Jacques Garaud, CEO of Inotrem said: *"These results are very encouraging for septic shock patients and confirms the therapeutic potential of our novel personalized approach based on immunomodulation targeting the TREM-1 pathway."*

Bruno François, MD, from the Limoges University Hospital, Coordinating Investigator of the study, added: *"These positive data open promising and interesting prospects on a severe and often life-threatening disease, that currently has no approved targeted therapy"*.

Inotrem previously announced it was granted access to EMA's priority medicines scheme (PRIME) for its lead compound nangibotide (LR12) in the treatment of septic shock. In parallel, Inotrem is developing in partnership with Roche Diagnostics a quantitative assay for the biomarker sTREM-1, paving the way to a personalized healthcare approach in critical care medicine.

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For more information about Inotrem's Phase 2a study, please refer to the abstract published in *Intensive Care Medicine Experimental*: <https://icm-experimental.springeropen.com/articles/10.1186/s40635-018-0196-z>

#### **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. TREM-1 pathway is an amplification loop of the immune response that triggers an exuberant and hyperactivated immune state which is responsible for the onset and progression of sepsis. In preclinical septic shock models, nangibotide was able to restore appropriate inflammatory response, vascular function, and improved animals' survival post septic shock.

#### **About Inotrem**

Inotrem S.A. is a biotechnology company specialized in for the control of acute inflammatory syndromes, such as septic shock. 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 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 investors — Sofinnova Partners, Andera Partners (previously Edmond de Rothschild Investment Partners), Biomed Invest and Inserm Transfert Initiative. [www.inotrem.com](http://www.inotrem.com)

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