Inotrem Unveils Game-Changing Precision Medicine Strategy for Nangibotide Clinical Development in Septic Shock

Published in Intensive Care Medicine, Inotrem's results highlight the pivotal role of the soluble TREM-1 biomarker in identifying high-risk septic shock patients and guiding targeted treatment with nangibotide.

Paris, July 23rd, 2025 – Inotrem, a clinical-stage biotechnology company specialized in immunotherapy for acute inflammatory conditions, announces the publication of its precision medicine strategy for its leading drug candidate nangibotide, a first-in-class TREM-1 inhibitor in septic shock. This work has been published in *Intensive Care Medicine*[1], one of the most prestigious journals in the field of critical care medicine.

The article, titled *"A mechanism-based prognostic enrichment strategy for the development of the TREM-1 inhibitor nangibotide in septic shock,"* confirms the central role of the soluble TREM-1 (sTREM-1) biomarker as a valuable precision medicine tool in acute care. High levels of this marker identify the most critically ill patients developing severe organ failure and with the highest risk of dying. When administered on top of standard of care, nangibotide significantly improves clinical outcome in this patient population.

"*This is a breakthrough precision medicine approach in septic shock*," **said Dr. Bruno François from Limoges University Hospital, lead author of the article and Coordinating Investigator of the phase 2b clinical program**. "*Our findings confirm the efficacy of nangibotide in an enriched patient population with elevated levels of the sTREM-1 biomarker, thus linking the targeted pathway dysregulation, septic shock severity, and drug mechanism of action*."

sTREM-1 biomarker positive patients do not respond to current standard of care and nangibotide administration resulted in a statistically significant improvement in organ function (primary endpoint: change in sequential organ failure assessment score from baseline to day 5, d=-2.5pts in favor of nangibotide vs placebo, p=0.007) and an increase in shock reversal (d=+22.2%, p=0.006). In addition, the study demonstrated shorter stay in intensive care unit and improved long-term outcomes including lower morbidity and mortality. These findings support the therapeutic potential of nangibotide as a precision immunomodulatory treatment. No safety concerns have been identified with nangibotide.

"*With these results, we are entering a new paradigm for drug development in intensive care*," stated **Sven Zimmermann, CEO of Inotrem**. "*This prognostic enrichment strategy has been agreed with the 3 main regulatory agencies FDA, EMA, and PMDA and paves the way for the future development of nangibotide.*

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[1] https://pubmed.ncbi.nlm.nih.gov/40323456/

About Septic Shock

Septic shock is the most severe complication of sepsis, caused by an uncontrolled immune response leading to acute organ failure. It affects over 1.1 million people each year in the US and 5 main EU countries, with mortality rates up to 40%. Despite its burden, management of septic shock remains limited to management of symptoms and no causal treatment exists, leaving a significant unmet medical need.

About TREM-1 and nangibotide

TREM-1 is an immune amplifier that is upstream of most known inflammatory pathways and is a crucial mediator of immune dysregulations in acute inflammatory diseases, including septic shock.

Nangibotide is a first-in-class immunomodulatory peptide that selectively inhibits the TREM-1 pathway. It is being developed to restore immune balance and vascular function in life-threatening inflammatory conditions such as septic shock. Nangibotide has demonstrated a favorable safety profile and consistent signals of efficacy in biomarker-defined populations. Nangibotide has been labelled PRIME (PRIority Medicine) by the European Medicine Agency (EMA) and has received Fast Track designation by the U.S. Food and Drug Administration (FDA). Regulatory path up to registration has been agreed with the FDA, EMA, and PMDA.

About Inotrem

Founded in 2013, Inotrem S.A. is a clinical-stage biotechnology company developing immunotherapies for acute inflammatory diseases. Its proprietary technology platform targets the TREM-1 pathway to modulate immune dysregulation. The company was co-founded in 2013 by Dr. Jean-Jacques Garaud (former Head of R&D at Roche), Prof. Sébastien Gibot, and Dr. Marc Derive. Inotrem is supported by leading European and North American investors.

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