



## **Policy for Expanded Access / Compassionate Use of Nangibotide**

INOTREM SA is a biotechnology company specialized in immunotherapy for acute and chronic inflammatory syndromes via immunomodulation that targets the TREM-1 pathway to control unbalanced inflammatory responses.

The company's lead candidate is nangibotide, which is currently being developed for the treatment of septic shock. This development is being conducted through clinical trials. If successful, these may provide the basis for submissions for drug approval to regulatory authorities, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

INOTREM believes that participation in controlled clinical trials at this point in time the most adequate way of providing access to eligible patients with nangibotide. Clinical trials are conducted according to current state of the art and in compliance applicable regulations.

Details about our clinical trials, including eligibility requirements for participating in ongoing or planned studies are published in public databases such as [clinicaltrials.gov](http://clinicaltrials.gov) and [clinicaltrialsregister.eu](http://clinicaltrialsregister.eu).

We recognize that there may be patients with septic shock or a related condition for whom participation in a clinical trial may not be an option. Where allowed, such patients may be interested in seeking access to investigational drugs before the regulatory approval of a drug via compassionate use or expanded access. Providing access outside of controlled clinical trials at this time could jeopardize the conduct of these trials and thus even prevent or delay access to nangibotide for other patients in need. Also, in consideration of the currently limited available data on safety and efficacy of nangibotide, INOTREM's current policy is that it is not appropriate and premature to provide access to nangibotide outside of our controlled clinical trials at this point in time.

This policy may be reviewed and amended in the future. For additional information about this policy, please contact [contact@inotrem.com](mailto:contact@inotrem.com). We aim to provide responses within one week.