

## PRESS RELEASE

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### Results from EMBRACE Phase 2a study of emapalumab in interferon-gamma-driven sepsis presented at ISICEM

- Primary endpoint: improvement in organ function observed in 60% of patients receiving high-dose emapalumab vs 40% with standard of care plus placebo
- 28-day mortality: 40% in the high-dose emapalumab group vs 52% in the placebo group
- Biomarker response: high-dose emapalumab associated with faster reduction of pro-inflammatory biomarkers linked to interferon-gamma signalling
- Emapalumab was generally well tolerated

Sobi® (STO: SOBI) today announced that topline results from the Phase 2a EMBRACE study (NCT06694701), evaluating Gamifant® (emapalumab) in patients with interferon-gamma (IFN $\gamma$ )-driven sepsis (IDS), were presented at the International Symposium on Intensive Care and Emergency Medicine (ISICEM) by Professor Evangelos J. Giamarellos-Bourboulis, President of the Hellenic Institute for the Study of Sepsis. The EMBRACE study was sponsored by the Hellenic Institute for the Study of Sepsis (HISS) as part of a research collaboration with Sobi.

“These findings support the concept that sepsis is not a single disease but a syndrome with different biological drivers,” said Prof. Evangelos J. Giamarellos-Bourboulis, principal investigator of the EMBRACE study. “The EMBRACE study explores a precision medicine approach in which patients with interferon-gamma-driven immune dysregulation may benefit from targeted immunotherapy.”

Sepsis is a life-threatening condition caused by a dysregulated immune response to infection that can lead to organ failure and death. The EMBRACE Phase 2a study evaluated emapalumab in patients with IDS identified through biomarker profiling.

“Sepsis represents a leading cause of mortality worldwide and treatment options remain limited<sup>1</sup>. The interferon-gamma driven sepsis endotype shows an elevated mortality risk compared to all sepsis patients,” said Lydia Abad-Franch, Chief Medical Officer and Head of Research & Development at Sobi. “We are encouraged by these data and are discussing the next steps in the clinical program with regulatory authorities to gather further evidence to evaluate a potential new indication for emapalumab.”

Emapalumab was generally well tolerated in the EMBRACE study. The safety observations were consistent with the known safety profile of emapalumab, with infections the most common events observed, and no new safety signals identified.

### About sepsis and IFN $\gamma$ -driven sepsis (IDS)

Sepsis is a serious condition in response to an infection that can lead to organ failure and is a leading global cause of mortality. A recent large study, published in [eBioMedicine in 2024](#) describes different sepsis endotypes, suggesting varying endotypes require differentiated treatment strategies. Approximately 20% of the patients studied are of the newly described IFN $\gamma$ -driven sepsis (IDS) endotype.

### About the EMBRACE study

The EMBRACE study (NCT06694701) was a Phase 2a, double-blind, randomised controlled trial conducted at 24 sites in Greece. The study was sponsored by the Hellenic Institute for the Study of Sepsis (HISS) as part of a research collaboration with Sobi. The trial investigated whether Gamifant, an anti-IFN $\gamma$  antibody, can improve clinical outcomes in patients with the interferon gamma-driven sepsis (IDS) endotype and absence of sepsis-induced immunoparalysis. IDS is characterised by elevated levels of CXCL9 and detectable IFN $\gamma$  and is associated with poor patient outcomes. By targeting this inflammation pathway, the EMBRACE trial aimed to reduce mortality, improve organ function, and accelerate recovery. The trial design includes three arms (a total of 75 patients enrolled), two groups receiving Gamifant, (low and high doses) alongside standard-of-care treatment, and one group receiving placebo alongside standard-of-care treatment. The primary endpoint was a  $\geq 1.4$ -point decrease in the Sequential Organ Failure Assessment (SOFA) score from baseline to the end of treatment (28 days). Secondary endpoints include 28-day mortality, safety, pharmacokinetics, and changes in key inflammatory biomarkers such as CRP, IL-6, ferritin, IFN $\gamma$ , and CXCL9.

### About Gamifant

Gamifant<sup>®</sup> (emapalumab) is an anti-interferon gamma (IFN $\gamma$ ) monoclonal antibody that binds to and neutralises IFN $\gamma$ . When IFN $\gamma$  is secreted in an uncontrolled manner, hyperinflammation occurs within the body. Gamifant is indicated for administration through intravenous infusion over one hour twice per week until haematopoietic stem cell transplantation (HSCT). In the USA, Gamifant is indicated for the treatment of adult and paediatric (newborn and older) patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy. Gamifant is also approved in the US for the treatment of adult and paediatric (newborn and older) patients with haemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

### About HISS

The Hellenic Institute for the Study of Sepsis (HISS) is a non-profit, academic institute which fosters the activities of young researchers in the fields of systemic inflammation and sepsis. Since 2010, HISS has published 125 peer-reviewed publications including the publication of guidelines for sepsis in Greece, led the organisation of 15 conferences, and of 35 clinical studies. HISS focuses on precision immunotherapy and is the Sponsor of the major randomised controlled trials SAVE-MORE and ImmunoSep. The data from these studies have been published in journals such as *Nature Medicine* and *JAMA*.<sup>2,3</sup> For more information, please visit <https://sepsis.gr>.

### About Sobi<sup>®</sup>

Sobi<sup>®</sup> is a global biopharma company unlocking the potential of breakthrough innovations, transforming everyday life for people living with rare diseases. Sobi has approximately 1,900 employees across Europe, North America, the Middle East, Asia and Australia. In 2025 revenue amounted to SEK 28 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at [sobi.com](https://sobi.com) and [LinkedIn](#).

### Contacts

For details on how to contact the Sobi Investor Relations Team, please click [here](#). For Sobi Media contacts, click [here](#).

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<sup>i</sup> Rudd KE et al. *Global, regional, and national sepsis incidence and mortality, 1990–2017*. The Lancet, 2020;395:200–211.