PRESS RELEASE

Stockholm, Sweden, 19 March 2025

Sobi announces a new research collaboration on the development of Gamifant® (emapalumab) in sepsis, which is to be presented at the ISICEM congress

Sobi® (STO: SOBI), today announced a research collaboration involving a new Phase 2a clinical trial for Gamifant® (emapalumab) for the potential treatment of interferon-gamma (IFNγ)-driven sepsis (IDS) which is to be presented at the International Symposium on Intensive Care and Emergency Medicine (ISICEM) Congress by Prof. Giamarellos-Bourboulis, from the Hellenic Institute for the Study of Sepsis. The study underscores Sobi's commitment to advancing medicine through targeted therapies for severe and complex conditions such as sepsis, a leading cause of mortality globally.

Key Highlights

- IDS is a new endotype representing approximately 20 percent of sepsis patients and is characterised by detection of IFNγ (above lower limit of detection) and elevated levels of the chemokine CXCL9.
- The EMBRACE phase 2a study will investigate the potential of Gamifant® (emapalumab) in treating a subgroup of sepsis patients driven by the IDS endotype and absence of sepsis-induced immunoparalysis.
- IDS patients with a low human leukocyte antigen DR (HLA-DR) expression on monocytes characteristic of immunoparalysis will not be included into the EMBRACE study. The potential inclusion of this IDS sub-population into further studies will be evaluated based on the results of EMBRACE.

The EMBRACE phase 2a trial (NCT06694701) was approved in March 2025. The first trial sites have been initiated, and patient screening to identify eligible patients with IDS has started.

The trial design is to be presented at ISICEM by Prof. Evangelos Giamarellos-Bourboulis, MD, PhD, FISAC, principal investigator and sponsor of the EMBRACE study, from the Hellenic Institute for the Study of Sepsis (HISS): ”The EMBRACE Phase 2a study will adopt a precision immunotherapy approach for the treatment of sepsis driven by the IDS endotype, a patient group currently having limited therapeutic choices.”

“We are looking forward to this research collaboration on the use of Gamifant® (emapalumab) in the new endotype of interferon gamma-driven sepsis,” said Lydia Abad-Franch, MD, Head of Research & Development and Medical Affairs and Chief Medical Officer at Sobi. “We are committed to advancing science and study Gamifant® (emapalumab) in indications with a high unmet need and where excessive interferon gamma production plays a key role in driving hyperinflammation.”

Presentation details
Emapalumab treatment for anticipated clinical benefit in sepsis driven by the interferon-gamma endotype (the EMBRACE trial): O Konstantinidou, E Olntasi, H Florou, A Reininger, E Giamarellos-Bourboulis, F EMBRACE STUDY GROUP. ISICEM 2025; Abstract number A173; Poster number P249.

About sepsis and IFNγ-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[1], describes different sepsis endotypes, suggesting varying endotypes require differentiated treatment strategies. Approximately 20% of the patients studied are of the newly described IFNγ-driven sepsis (IDS) endotype. IDS is marked by elevated levels of CXCL9 and detection of IFNγ and poor clinical outcomes, with a 28-day mortality rate ranging from 40 to 43%.

About the EMBRACE study
The **EMBRACE study** (NCT06694701) is a Phase 2a, double-blind, randomized controlled trial planned to be conducted at 24 sites in Greece. The trial investigates whether Gamifant® (emapalumab), an anti-IFNγ antibody, can improve clinical outcomes in patients with the interferon-gamma-driven sepsis (IDS) endotype and absence of sepsis-induced immunoparalysis. IDS is characterized by elevated levels of CXCL9 and detectable IFNγ and is associated with poor patient outcomes. By targeting this inflammation pathway, the EMBRACE trial aims to reduce mortality, improve organ function, and accelerate recovery.
The trial design includes three arms, and plans to enrol 75 patients, two groups receiving Gamifant® (emapalumab), (low and high doses) alongside standard-of-care treatment, and one group receiving placebo alongside standard-of-care treatment. The primary endpoint is a ≥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, IFNγ, and CXCL9.

About Gamifant® (emapalumab)
Gamifant® (emapalumab) is an anti-interferon gamma (IFNγ) monoclonal antibody that binds to and neutralises IFNγ. In the USA, Gamifant® (emapalumab) 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. Primary HLH is a rare syndrome of hyperinflammation that usually occurs within the first year of life and can rapidly become fatal unless diagnosed and treated. The FDA approval is based on data from the phase 2/3 studies (NCT01818492 and NCT02069899). Gamifant® (emapalumab) is indicated for administration through intravenous infusion over one hour twice per week until haematopoietic stem cell transplantation (HSCT)

About Sobi®
Sobi® is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology, and specialty care. Sobi has approximately 1,800 employees across Europe, North America, the Middle East, Asia, and Australia. In 2024, revenue amounted to SEK 26 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn.

1: Interferon-gamma driven elevation of CXCL9: a new sepsis endotype independently associated with mortality Giamarellos-Bourboulis, Evangelos J. et al. eBioMedicine, Volume 109, 105414

Contacts
For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.