PRESS RELEASE

Stockholm, 20 May 2021

Early use of anakinra reduces risk of mortality for patients with COVID-19 pneumonia, reduces ICU admission and increases likelihood of full recovery

- Day 28 full results from the SAVE-MORE study show early treatment with anakinra plus SOC (standard of care) reduced mortality by 55% and reduced average time until ICU (intensive care unit) discharge by four days
- In patients treated with anakinra plus SOC, overall clinical status improved by 64% compared to those treated with SOC alone
- The SAVE- MORE trial, conducted by the Hellenic Institute for the Study of Sepsis, is the first large, pivotal randomised controlled trial to specifically evaluate a target patient population with COVID-19 at risk of progressing and demonstrating the benefit of earlier intervention with anakinra for the prevention of disease progression and reduced risk of mortality

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) and the Hellenic Institute for the Study of Sepsis today announced positive day 28 full results from the investigator-sponsored SAVE-MORE study[i]. SAVE-MORE found that early and targeted use of anakinra, in addition to current SOC, showed a 55% relative reduction in mortality and near threefold benefit in preventing progression to severe respiratory failure (SRF) in hospitalised COVID-19 patients with poor prognosis. Anakinra treatment also increased the number of patients discharged from hospital with no evidence of COVID-19 infection, with patients being 2.8 times more likely to fully recover than patients who received placebo and SOC. Results from the study, which included over 600 patients, were released on MedRxiv and have been submitted for peer-reviewed publication.

SAVE-MORE is the first study to specifically evaluate COVID-19 patients at risk of SRF prior to ICU admission with the objectives of preventing disease progression or death and enhancing disease resolution. The trial assessed patients with moderate or severe pneumonia and specifically identified those at risk of SRF by the measurement of elevated suPAR (soluble urokinase plasminogen activator receptor), a plasma biomarker and prognostic tool that reflects early immune activation and has been previously associated with poor prognosis in various conditions. Co-administered treatments were similar between the two arms and included dexamethasone, anticoagulants and remdesivir.

“With excessive inflammatory response to COVID-19 infection being a leading cause of disease progression and mortality, there is an urgent need for medications that can target this hyperinflammation and prevent its evolution. The SAVE-MORE trial confirms a significant reduction in COVID deaths of 55% and also the prevention of severe respiratory failure and ICU admission in at risk patients with COVID related pneumonia, when treated early with anakinra and standard of care versus standard of care alone. The results show that the risk of critical illness can be reduced through early treatment,” said lead investigator Evangelos J.

Giamarellos-Bourboulis, Professor of Internal Medicine and Infectious Diseases, National and Kapodistrian University of Athens, President of the European Shock Society, and Chairman of the European Sepsis Alliance.

COVID-19 infection can be severe and lead to death due to an overreaction of the infected person's inflammatory response, often referred to as a "cytokine storm". Anakinra, an anti-inflammatory drug that targets the cytokines IL-1α/β, which plays an important role in COVID-19-induced hyperinflammation. Blocking IL-1α/β at an early stage of disease can have an important impact on COVID-19 disease progression. To date, no drug has been approved for the treatment of the COVID-19 inflammatory response.

"At a time when many countries face huge pressures as they care for extremely ill COVID-19 patients, we are pleased to announce the day 28 full results of the SAVE-MORE study which shows the potential of anakinra to improve patients' clinical condition when treatment is initiated early and before they require respiratory support. Sobi looks forward to continued dialogue with the EMA and other regulatory agencies regarding these results," said Guido Oelkers, CEO of Sobi.

Analysis of the primary end point, the comparative 11-point WHO Clinical Progression Scale (CPS)[ii], measured patient illness by tracking progress through the healthcare system. At day 28, overall clinical status improved significantly in patients with severe COVID pneumonia likely to progress to SRF receiving SOC plus anakinra vs patients receiving SOC plus placebo (Odds Ratio 0.36, $p<0.0001$).

For the same group of anakinra treated patients there were reductions in the number of patients who progressed to SRF or death (Odds Ratio 0.46, $p<0.01$), as well as an increase in the number of patients who were discharged from hospital with no evidence of COVID-19 infection (Odds Ratio 0.36, $p<0.0001$). 28-day mortality was also 55% lower among patients allocated to SoC and anakinra treatment. The positive changes to overall improvement and reduced progression to SRF or death were apparent at day 14.

In the SAVE-MORE study, the incidence of serious treatment-emergent adverse events (TEAEs) was lower in patients treated with anakinra and SOC than patients who received SOC only. The incidence of non-serious TEAEs was similar in both treatment groups.

About SAVE-MORE

SAVE-MORE (NCT04680949); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19) is a large, pivotal, confirmatory, phase III randomized controlled trial (RCT) in over 600 hospitalised patients. The trial aims to evaluate the efficacy and safety of early start of anakinra guided by suPAR in patients with LRTI by SARS-CoV-2 in improving the clinical state of COVID-19 over 28 days, as measured by the ordinal scale of the 11-point World Health Organization (WHO) clinical progression scale (CPS). Anakinra was administered at a dose of 100mg/day SC for up to 10 days. Of 1,060 patients screened, 606 patients were randomised across 40 sites in Greece and Italy. SAVE-MORE is an investigator-sponsored study conducted independently by Professor Giamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor. Sobi has supported the study with study drug and funding.

About SAVE

In the SAVE study (NCT04357366), patients with lower respiratory tract infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at high risk for progression to serious respiratory failure were detected using the suPAR biomarker. Early treatment began with anakinra 100 mg/day SC for up to 10 days in the effort to prevent progression in serious respiratory failure. The study is open label, single arm and will include a total of 1,000 patients. 130 patients were included in a preliminary analysis. The analysis of the SAVE study at Day 14 showed that

early treatment with anakinra as guided by the suPAR biomarker significantly decreased the incidence of severe respiratory failure in COVID-19 patients with pneumonia compared to a matched control cohort[iii]. The SAVE study is an investigator sponsored study conducted independently by Professor Giamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor[iv]. Sobi has supported the study with study drug and funding.

About Kineret® (anakinra)
Kineret® is an interleukin-1 α and β receptor antagonist that is indicated in the US for reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs), for the treatment of neonatal-onset multisystem inflammatory disease (NOMID, a form of cryopyrin-associated periodic syndromes (CAPS)), and for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

In Europe, Kineret is indicated in adults for the treatment of the signs and symptoms of rheumatoid arthritis (RA) in combination with methotrexate, with an inadequate response to methotrexate alone. In addition, Kineret is indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of cryopyrin-associated periodic syndromes (CAPS), including - neonatal-onset multisystem inflammatory disease (NOMID)/chronic infantile neurological, cutaneous, and articular syndrome (CINCA), Muckle-Wells syndrome (MWS) and familial cold auto inflammatory syndrome (FCAS). Kineret is indicated for the treatment of Familial Mediterranean fever (FMF). Kineret should be given in combination with colchicine, if appropriate. It is also indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Kineret can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying antirheumatic drugs (DMARDs).

For full US prescribing information visit www.kineretrx.com and for full European prescribing information visit the EMA website. Anakinra has not been approved for the treatment of COVID -19.

About suPAR and suPARnostic®
suPAR (soluble urokinase plasminogen activator receptor) is the biomarker detected by ViroGates' suPARnostic® products and is a protein in plasma, measurable in every human being. suPAR is considered a general risk status biomarker indicating disease presence, disease severity and progression, organ damage and mortality risk across disease areas such as cardiovascular diseases, kidney diseases, type 2 diabetes, cancer, etc.

About the Hellenic Institute for the Study of Sepsis
The Hellenic Institute for the Study of Sepsis (HISS) is a non-profit organisation situated in Athens. HISS coordinates the research activities in sepsis and severe inflammatory disorders since 2010 of 58 departments of Internal Medicine and Intensive Care Units in Greece and abroad. HISS has sponsored the conduct of more than 30 clinical studies and has a track record of providing support for more than 100 publications. The phase II SAVE trial and the phase III SAVE-MORE trial were regulatory sponsored by HISS. For more details visit www.sepsis.gr
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About Sobi
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,500 people across Europe, North America, Middle East, and Asia. In 2020, Sobi's revenue amounted to SEK 15.3 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at sobi.com**.**

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[i] https://medrxiv.org/cgi/content/short/2021.05.16.21257283v1
[ii] Lancet Infect Dis 2020, Published Online June 12, 2020 https://doi.org/10.1016/ S1473-3099(20)30483-7
[iii] Early suPAR-guided anakinra decreased SRF and restored the pro-/anti-inflammatory balance