PRESS RELEASE

Stockholm, 3 May 2021

Sobi and Hellenic Institute for the Study of Sepsis report use of anakinra improved overall clinical outcomes by 64% in hospitalised patients with COVID-19 pneumonia

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) and the Hellenic Institute for the Study of Sepsis today announced positive top line results from the Investigator-sponsored SAVE-MORE study, which assessed the effect of anakinra in moderate to severe COVID-19 pneumonia patients. Early and targeted use of anakinra in addition to current standard of care in hospitalised patients with poor prognosis prevented either death or progression to severe respiratory failure, whilst increasing the number of patients who were discharged from hospital with no evidence of COVID-19 infection.

SAVE-MORE is a large, randomised controlled trial in over 600 hospitalised patients that specifically identifies those at risk of severe respiratory failure by the measurement of elevated suPAR (soluble urokinase plasminogen activator receptor), a plasma biomarker that reflects immune activation and has been previously associated with poor prognosis in a number of conditions. The study is sponsored by the Hellenic Institute for the Study of Sepsis (HISS) in Greece and led by its President and Chairman, Professor Evangelos J. Giamarellos-Bourboulis. Giamarellos-Bourboulis is Professor of Internal Medicine and Infectious Diseases at the National and Kapodistrian University of Athens, President of the European Shock Society and Chairman of the European Sepsis Alliance. Sobi intends to discuss these results with regulatory authorities to evaluate the possibility of approval.

Analysis of the primary end point, the comparative 11-point WHO Clinical Progression ordinal Scale (CPS)[i], at day 28 demonstrated significant improvement in patients receiving standard-of-care treatment plus anakinra vs patients receiving standard-of-care plus placebo (Odds Ratio 0.36, $p<0.001$). There were reductions in the number of patients who died or who progressed to severe respiratory failure, as well as an increase in the number of patients who were discharged from hospital with no evidence of COVID-19 infection. These changes were apparent at day 14 (Odds Ratio 0.59, $p= 0.001$).

“This is the first study to specifically evaluate an at-risk patient population before admission to intensive care unit (ICU). The results provide a significant step forward in the search for additional treatment options to prevent progression to a more critical state,” said Professor Giamarellos-Bourboulis. “My thanks go to the many patients and clinicians who have contributed across Italy and Greece.”

“We are pleased that anakinra demonstrated a significant benefit on top of standard of care across a wide range of clinical outcomes” said Guido Oelkers, CEO of Sobi. “I would like to congratulate Professor Giamarellos-Bourboulis and his collaborators for conducting such impressive work under challenging conditions in such a short period of time.”

"It is clear that there is still a considerable unmet medical need for COVID-19 despite recent advances in treatment," said Ravi Rao, Head of Research & Development and Chief Medical Officer at Sobi. "These important data come at a critical time and we plan to continue our ongoing dialogue with EMA in collaboration with Professor Giamarellos-Bourboulis."

About SAVE-MORE
SAVE-MORE (NCT04680949); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19) is a pivotal, confirmatory, phase III randomized controlled trial (RCT). 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 cohortii. 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[iii]. Sobi has supported the study with study drug and funding.

About Kineret® (anakinra)
Kineret® is a interleukin-1 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.

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**.**

This information is information that Swedish Orphan Biovitrum AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out below, at 9:00 CEST on 3 May 2021.

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