PRESS RELEASE

Stockholm, Sweden, 16 December 2021

Kineret® (anakinra) receives positive opinion from the CHMP for treatment of patients with COVID-19 pneumonia

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) today announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion of Kineret® (anakinra) for the treatment of coronavirus disease 2019 (COVID-19) in adult patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure determined by plasma concentration of soluble urokinase plasminogen activator receptor (suPAR) ≥ 6ng/ml. EMA has recommended approval for use of Kineret in COVID-19 to the European Commission which will issue a final decision.

COVID-19 infection can lead to death due to an overreaction of the infected person's inflammatory response, often referred to as a 'cytokine storm'[i]. Anakinra is an anti-inflammatory therapy that targets the cytokines IL-1α/β, which play a role in COVID-19-induced hyperinflammation. Blocking IL-1α/β before the hyperinflammatory phase can have an important impact on COVID-19 disease progression[ii].

The positive opinion is based on results from the SAVE-MORE phase 3 study which found that early identification of candidate patients with suPAR followed by treatment with anakinra resulted in a 64% relative reduction of patients progressing into severe disease and death, in a 55% relative decrease in mortality, which reached 80% relative decrease in mortality for patients with cytokine storm. Results were published in Nature Medicine on 3 September 2021.

The SAVE-MORE study used learning from previous trials and demonstrated the effectiveness of anakinra therapy in patients who had not yet progressed to severe respiratory failure but had poor prognosis, identified by a plasma biomarker of inflammation.

"At a time when many countries still face enormous pressure as they continue to care for extremely ill patients, today's positive opinion from the CHMP represents an important milestone for the treatment of COVID-19. If approved by the European Commission, this will be welcome news for many across Europe," said Ravi Rao, Head of Research & Development and Chief Medical Officer at Sobi.

"I would like to congratulate Professor Giamarellos-Bourboulis and his collaborators for conducting this impressive work under such challenging conditions. We look forward to ongoing dialogue with other regulatory agencies to ensure anakinra is available to patients with COVID-19 pneumonia," said Guido Oelkers, CEO of Sobi.

"I would like to thank all the collaborators, the patients and their relatives who contributed to the advancement of science and treatment of COVID patients with appropriate care during the SAVE-MORE study," said Lead Investigator, Evangelos J. Giamarellos-Bourboulis Professor at the National and Kapodistrian University of Athens and President of the Hellenic Institute for the Study of Sepsis.

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.

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 aimed 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 ProfessorGiamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor. Sobi has supported the study with study drug and funding.

SAVE-MORE found that treatment with Kineret in addition to standard of care showed considerable efficacy, reducing the risk of disease progression and death by 64 per cent compared to standard of care alone. Overall, there was a significant improvement of the clinical status by Day 28 compared to placebo (OR: 0.36 [95% CI 0.26 to 0.50] P<0.001) and this improvement was seen by Day 14.

The treatment benefit of Kineret was supported by increase in the number of patients fully recovered (50.4% and 26.5%) and significantly reduction of risk of death by 55% by day 28 compared to placebo (HR: 0.45, 95% CI 0.21–0.98, P = 0.045). No new safety signals or safety concerns were observed from the use of Kineret for treatment of COVID-19.

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 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.grContact details: Evangelos J. Giamarellos-Bourboulis egiamarel@med.uoa.gr; Leda Efstratiou insepsis@otenet.gr

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. Sobi employs approximately 1,500 people across Europe, North America, the Middle East, Russia and Asia. In 2020, Sobi's revenues amounted to SEK 15.3 billion. Sobi's share (STO: SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

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 15:00 CET on 16 December 2021.

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[i] https://www.frontiersin.org/articles/10.3389/fimmu.2020.570993/full.
ii Kyriazopoulou, E., Poulakou, G., Milionis, H. et al. Early treatment of COVID-19 with anakinra guided by soluble urokinase plasminogen receptor plasma levels: a double-blind, randomized controlled phase 3 trial. Nat Med 27, 1752–1760 (2021). https://doi.org/10.1038/s41591-021-01499-z.