# PRESS RELEASE

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## Kineret® authorised for emergency use by FDA for the treatment of COVID-19 related pneumonia

Sobi® today announced that the US Food and Drug Administration has granted Emergency Use Authorisation (EUA) for the use of Kineret® (anakinra) for the treatment of coronavirus disease 2019 (COVID-19) in hospitalised adults with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure.

COVID-19 can progress to severe respiratory failure and death due to an excessive inflammatory response [1]. Kineret is an anti-inflammatory medicine that neutralises the biological activity of both cytokines IL-1α and β, which play a role in COVID19-induced hyperinflammation[2]. Blocking these cytokines early in the course of the hyperinflammatory phase can have an important impact on COVID-19 disease progression[3].

Kineret was shown to improve outcomes, reduce progression to severe respiratory failure and mortality in patients hospitalised with COVID-19 pneumonia requiring supplemental oxygen, and the benefits were maintained long-term.

“This is another important milestone for Sobi. The authorisation will provide both patients and treating physicians in the US with a treatment option against COVID-19 related pneumonia,” said Anders Ullman, Head of Research & Development and Chief Medical Officer at Sobi.

The authorisation was based on results from the SAVE-MORE phase 3 study which were published in Nature Medicine on 3 September 2021.

**About Emergency Use Authorisation status**

Kineret (anakinra) has not been approved but has been authorised for emergency use for the treatment of coronavirus disease 2019 (COVID-19) in hospitalised adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR). The emergency use of Kineret is only authorised for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorisation revoked sooner. See full fact sheet for healthcare providers for the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19.

**About SAVE-MORE and patient population identification**

SAVE-MORE (NCT04680949); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19 was a pivotal, confirmatory, phase 3 double-blind randomised controlled study. The study evaluated the efficacy and safety of early start of Kineret guided by suPAR in patients with lower respiratory tract infection 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 clinical progression scale. Kineret 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 was an investigator-sponsored study conducted independently by Professor Evangelos J. Giamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor. The study protocol and the full statistical analysis plan was developed after advice from the COVID-Emergency Task Force of the EMA. Sobi has supported the study with study drug and funding.

The suPAR assay is not commercially available in the US. In order to identify a comparable population as was studied in the SAVE-MORE trial, an alternative patient identification method was developed to select patients most likely to have suPAR ≥ 6 ng/mL based on commonly measured patient characteristics. Patients meeting at least three of the following eight criteria are considered likely to have suPAR ≥ 6 ng/mL at baseline.

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1. Age ≥ 75 years
2. Severe pneumonia by WHO criteria[4]
3. Current/previous smoking status
4. Sequential Organ Failure Assessment (SOFA)[5] score ≥ 3
5. Neutrophil-to-lymphocyte ratio (NLR) ≥ 7
6. Haemoglobin ≤ 10.5 g/dL
7. Medical history of ischemic stroke
8. Blood urea ≥ 50 mg/dL and/or medical history of renal disease

**About Kineret®**
Kineret (anakinra) is an interleukin-1α 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 (RA), 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 the EU, 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). Kineret is indicated 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) ≥ 6 ng/ml.

For full US prescribing information please visit https://kineretrxhcp.com/pdf/Full-Prescribing-Information-English.pdf and for full EU prescribing information please visit the EMA website.

**References**
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**Sobi®**
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Providing sustainable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East and Asia. In 2021, revenue amounted to SEK 15.5 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

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