# PRESS RELEASE

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## Kineret® (anakinra) receives a positive opinion from CHMP for the treatment of Still's disease

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for anakinra for the treatment of Still's disease. The opinion is now referred to the European Commission for a decision.

Still's disease is a rare systemic multi-organ disorder of auto-inflammatory nature that affects both children and adults. It is often associated with fever, rash and joint inflammation. Still's disease is also referred to as systemic juvenile idiopathic arthritis or adult-onset Still's disease.

"We are very pleased with the CHMP positive opinion which recommends including this indication for Kineret in the EU. Sobi is committed to improving the lives of people affected by rare diseases, and this recommendation, if approved by the European Commission, would help address an unmet medical need for people with Still's disease," says Milan Zdravkovic, Chief Medical Officer and Head of Research and Development at Sobi.

In addition to current indications, the proposed new indication reads;
"*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 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).*"

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**About Still's disease**

Adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) are rare systemic disorders of auto-inflammatory nature. They share common clinical manifestations such as daily spiking fever, typical transient cutaneous rash, arthritis, lymphadenopathy, hepatosplenomegaly and serositis.

**About Kineret® (anakinra)**

Kineret® is an interleukin-1 receptor antagonist that in the US is indicated 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), and for the treatment of neonatal-onset multisystem inflammatory disease (NOMID), a form of cryopyrin-associated periodic syndromes (CAPS).

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, articular syndrome (CINCA), Muckle-Wells syndrome (MWS) and familial cold auto inflammatory syndrome (FCAS).

Kineret is approved in Australia for the treatment of active SJIA in patients 2 years and above who have failed to respond adequately to non-biological DMARDs. Kineret is also indicated for the treatment of active adult rheumatoid arthritis (RA) in patients who have had inadequate response to one or more other DMARDs. Kineret should be given in combination with methotrexate. In addition, Kineret is indicated in adult and paediatric patients 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, articular syndrome (CINCA), Muckle-Wells syndrome (MWS), and familial cold auto inflammatory syndrome (FCAS).

For full European prescribing information visit the EMA website.

**About Sobi™**

Sobi™ is an international speciality healthcare company dedicated to rare diseases. Our vision is to be recognised as a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases.
The product portfolio is primarily focused on treatments in Haemophilia and Specialty Care. Partnering in the development and commercialisation of products in specialty care is a key element of our strategy. Sobi has pioneered in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2017, Sobi had total revenues of SEK 6.5 billion and approximately 850 employees. The share (STO:SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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