

PRESS RELEASE

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Kineret® (anakinra) approved in the EU for the treatment of Still's disease

[Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi™) announces that the European Commission (EC) has approved an extension of the indication for Kineret (anakinra) to include the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), in all 28 European Union (EU) member states.

Still's disease is a rare systemic multi-organ disorder of auto-inflammatory nature that affects approximately 25,000¹ children and adults in the EU. In children, Still's disease (SJIA) is the most severe form of arthritis. It is often associated with fever, rash and joint inflammation.

In addition to current indications, the 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)."

"We are very pleased with the approval of Kineret in Still's disease in EU. This allows us to address an important unmet medical need in this patient population. It includes an option for first line treatment as an alternative to steroid treatment", says Milan Zdravkovic, Chief Medical Officer and Head of Research and Development at Sobi.

The approval is based on data from clinical trials as well as data from scientific literature and meta-analyses of published data. Overall, the evaluation of the medicine is based on more than 400 patients with Still's disease. It shows the efficacy of anakinra in both paediatric and adult patients with Still's disease, with the majority of patients achieving remission as well as an improvement of the signs and symptoms associated with the condition.²

Safety data from the clinical trials and published literature in Still's disease, together with substantial safety data from post-marketing use of Kineret since 2002 in both Still's disease and other indications, show that the most common adverse events are reactions at the site of injection, headache and increased total blood cholesterol.³

"This approval is an important milestone for us. Kineret has long been recognised as an effective and safe treatment for rheumatoid arthritis and Cryopyrin-Associated Periodic Syndromes (CAPS). With this new indication, patients with Still's disease will get access to an alternative treatment with an established safety

profile. We will now focus on a fast launch in Europe, beginning with Germany, the UK, the Netherlands and the Nordics”, says Norbert Oppitz, Head of Specialty Care at Sobi.

About Still's disease

Still's disease includes 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)

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). 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 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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¹ Sobi internal estimates.

² [New treatment option for rare inflammatory disease, EMA Press release, 23 February 2018.](#)

³ European prescribing information, EMA website