

PRESS RELEASE

Stockholm, Sweden, 16 November 2017



First patient randomised in a phase 3 study evaluating safety and efficacy of anakinra in the treatment of Still's disease

[Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi™) announces that the first patient has been randomised in the phase 3 study anaSTILLS, to evaluate efficacy and safety of anakinra in the treatment of Still's disease.

The purpose of the study is to assess the efficacy and to evaluate the safety of anakinra in patients with newly diagnosed Still's disease, including systemic juvenile idiopathic arthritis (SJIA) and adult onset Still's disease (AOSD). The anaSTILLS study is a randomised, double-blind, multicentre study being conducted in North America studying two dose levels of anakinra, administered subcutaneously, in comparison to placebo. In total 81 individuals are planned to be randomised in the study.

"We are very pleased with having initiated this confirmatory clinical study investigating the safety and efficacy of anakinra in people with Still's disease. This is a disease affecting both young people and adults and is associated with a significant morbidity and with a large unmet medical need," says Milan Zdravkovic, Senior Vice President, Chief Medical Officer and Head of Research & Development at Sobi.

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

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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 US prescribing information visit www.kineretrx.com and for full European prescribing information visit the [EMA website](#).

About Sobi™

Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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This press release contains certain forward-looking statements about anakinra and Sobi's anticipated results of the anaSTILLs study. These statements reflect Sobi's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug discovery and development. Except as required by law, Sobi undertakes no duty to update forward-looking statements to reflect events after the date of this release.