

PRESS RELEASE

Stockholm, 23 February 2016



Sobi™ to initiate clinical development programs in acute gout and Still's disease, and receives US patent on new formulation for Kineret® (anakinra)

[Swedish Orphan Biovitrum AB \(publ\) \(Sobi™\)](#), today announced that it has decided to initiate two clinical programs with Kineret® (anakinra) in North America, with the aim of evaluating two new potential indications for Kineret where a significant need for alternative treatment options exists: acute gout and Still's disease.

An increasing body of evidence suggests the potential involvement of interleukin-1 (IL-1) in a number of autoinflammatory diseases, including rare systemic inflammatory diseases such as Still's disease (systemic juvenile idiopathic arthritis and adult onset Still's disease), as well as more common autoinflammatory diseases such as acute gout.

"We look forward to initiating clinical trials to evaluate potential indications where patients need additional treatment options," says Kristina Timdahl, Medical Head Therapeutic Area Inflammation at Sobi. "We believe that there is a continued great potential for Kineret and are pleased to be able to further expand our strategic life-cycle development activities for the product in an effort to meet needs of the medical and patient communities."

The acute gout program will include a dose-finding phase 2 study, followed by a planned phase 3 study designed to evaluate the efficacy and safety of Kineret treatment in resolving the auto-inflammatory driven pain of acute flares. The Still's disease study is a phase 3 study designed to evaluate the efficacy and safety of Kineret in newly diagnosed adult and paediatric patients. The two clinical trials are expected to be initiated at the beginning of 2017 and take place primarily in North America. Both programs were reviewed in meetings with the US Food and Drug Administration (FDA) during 2015.

In addition, Sobi has been granted a US patent for a citrate-free formulation of anakinra which will expire in 2032. A corresponding patent has recently been allowed in Europe and may be granted in 2016. Sobi plans to work with the FDA and the European Medicines Agency (EMA) to define a pathway to integrate the new formulation to its manufacturing of Kineret in the future.

About acute gout

Acute gout is an autoinflammatory disease and an intensely painful and disabling inflammatory arthritis involving one or several joints. The goal of therapy in acute gout is prompt and safe termination of pain and disability. Gout is also a disease that is associated with multiple comorbidities, which may limit the use of some conventional treatment regimens.

About Still's disease

Still's disease is an auto-inflammatory disease that affects both children and adults, and is characterised by high spiking fevers, intermittent rash and arthritis. Still's disease is also referred to as systemic juvenile idiopathic arthritis or adult-onset Still's disease. For patients with Still's disease, there remains a high unmet need for a short-acting treatment option with a quick onset of efficacy and a well-established benefit:risk profile.

About Kineret®

Kineret® (anakinra) is a recombinant protein drug that blocks the biological activity of IL-1a and IL-1b by binding to interleukin-1 type 1 receptor (IL-1R1), expressed in a variety of tissues and organs, and thereby blocking the interleukin-1 (IL-1) signalling. IL-1 is a key mediator of inflammation and a significant contributor to autoinflammatory diseases. Kineret has a well-characterised safety profile, a quick onset of action and a short half-life.

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 for partner companies across Europe, the Middle East, North Africa and Russia. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 employees. The share (STO:SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

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