

## PRESS RELEASE

Stockholm, Sweden, 3 October 2018



### Results from the anaGO study – a phase 2 study with anakinra in patients with acute gout

[Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi™) releases the primary efficacy results from the phase 2 study with anakinra in patients with acute gout – the anaGO study. For the primary endpoint of patient assessed pain intensity in the most affected joint there was a substantial reduction from baseline, both following treatment with anakinra and the comparator triamcinolone. There was a clinically meaningful pain reduction with anakinra of around 50% and in line with expectations of IL-1 blockade in this disease. No statistically significant difference between the two treatments was obtained (primary endpoint). The well-established safety profile of anakinra was confirmed in the study. Sobi will continue to collect data from the extension phase of the phase 2 study to obtain further data in this patient population where further gout flares will be studied. Sobi plans to meet with the FDA to discuss options for moving anakinra forward into phase 3.

---

#### About acute gout

An auto inflammatory disease and intensely painful and disabling inflammatory arthritis involving one or several joints.

#### About anaGO

The anaGO study is a randomised, double-blind, active-control, multicentre, efficacy and safety study of two dose levels of subcutaneous anakinra for five days compared to a single dose of intramuscular triamcinolone in the treatment of acute gout. The initial phase of the study for the first gout flare is followed by an extension phase where additional flares occurring in the study population are treated until the last randomised patient has been followed for 1 year. The primary objective was to evaluate the efficacy with respect to patient-assessed pain intensity for up to 72 hours after initiation of dosing in the treatment of the first flare. Secondary endpoints included additional measures of efficacy as well as safety and tolerability.

The study randomised 165 patients for whom conventional therapy with NSAIDs and colchicine was contraindicated, not tolerated, or did not provide an adequate response. The patients were randomised to anakinra 100 mg/day, anakinra 200 mg/day, or one injection of triamcinolone 40 mg, in equally sized groups.

#### 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 1 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

#### Swedish Orphan Biovitrum AB (publ)

Postal address SE-112 76 Stockholm, Sweden

Phone: +46 8 697 20 00 | [www.sobi.com](http://www.sobi.com)

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).

Kineret is not approved for the treatment of acute gout.

For full US prescribing information visit [www.kineretrx.com](http://www.kineretrx.com) and for full European prescribing information visit the [EMA website](http://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 transform lives 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](http://www.sobi.com).

#### **For more information please contact**

Media relations

Linda Holmström, Senior Communications Manager

+46 708 734 095

[linda.holmstrom@sobi.com](mailto:linda.holmstrom@sobi.com)

Investor relations

Jörgen Winroth, Vice President, Head of Investor Relations

+1 347 224 0819, +1 212 579 0506

[jorgen.winroth@sobi.com](mailto:jorgen.winroth@sobi.com)

*This information is information that Swedish Orphan Biovitrum AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of Linda Holmström, Senior Communications Manager, at 08:00 CET on 3 October 2018.*