PRESS RELEASE

Stockholm, Sweden, 11 January 2017



First patient randomised in a phase II study evaluating the safety and efficacy of anakinra in the treatment of acute gout

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the first patient has been randomised in the phase II study (anaGO) to evaluate efficacy and safety of Kineret® (anakinra) in the treatment of acute gout.

The purpose of the study is to evaluate pain relief in people with acute gout who cannot take or have not previously responded to non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine. The anaGO study is a randomised, double-blind, multicentre study being conducted in North America studying two dose levels of anakinra (s.c.) in comparison to intramuscular triamcinolone. In total 159 individuals are planned to be randomised in the study.

"There is a persistent and significant unmet medical need for resolving pain in people affected by acute gout, and there is a strong scientific rationale for investigating the safety and efficacy of anakinra in this disease. Therefore we are very excited to have the first patient randomised in this important phase II study. We look forward to working with the study sites and plan to complete enrolment by the second half of 2017", says Milan Zdravkovic, Senior Vice President, Head of Research & Development at Sobi.

About acute gout

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

About Kineret®

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 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 not approved for the treatment of acute gout.

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 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

This press release contains certain forward-looking statements about anakinra and Sobi's anticipated results of the anaGO 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.

For more information please contact

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