

PRESS RELEASE

Stockholm, Sweden, 16 February 2021

Kineret® (anakinra) approved in Russia for the treatment of CAPS

Swedish Orphan Biovitrum AB (publ) (Sobi™) announces that the Ministry of Health of the Russian Federation has approved Kineret (anakinra) for the treatment of Cryopyrin associated periodic syndromes (CAPS).

“We are excited to announce the approval of this important treatment and we look forward to serving patients with CAPS in Russia,” said Norbert Oppitz, Head of Immunology and International at Sobi. “Today’s announcement also marks a significant milestone for Sobi’s future ambition, as Russia is a key market for our geographic expansion strategy over the next five years.”

CAPS are a group of rare genetic autoinflammatory diseases causing a number of inflammatory responses such as fever, pain sensitization, bone and cartilage destruction and acute plasma protein responses. In the most severe form of CAPS, known as Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological, Cutaneous, and Articular syndrome (CINCA), it is associated with increased mortality.

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 syndromes (CAPS), including - neonatal-onset multisystem inflammatory disease (NOMID)/chronic infantile neurological, cutaneous, and articular syndrome (CINCA), Muckle-Wells syndrome (MWS) and familial cold auto inflammatory syndrome (FCAS). Kineret is indicated for the treatment of Familial Mediterranean Fever (FMF). Kineret should be given in combination with colchicine, if appropriate. 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 US prescribing information visit www.kineretrx.com and for full European prescribing information visit the EMA website.

About CAPS

Cryopyrin associated periodic syndromes (CAPS) are a group of rare inherited autoinflammatory diseases caused by autosomal dominant mutations in a gene called NLRP3. CAPS is characterized by uncontrolled overproduction of IL-1beta. IL-1 induces a number of inflammatory responses such as fever, pain sensitization, bone and cartilage destruction and acute plasma protein responses. In the most severe form of CAPS, called Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular syndrome (CINCA), it is associated with increased mortality and fever, rash, chronic aseptic meningitis, sensorineural hearing loss, craniofacial abnormalities, and bone lesions. When of intermediate severity, called Muckle-Wells Syndrome (MWS), the disease is typically associated with episodic, intense and enduring flares and morbidity, including progressive hearing loss and kidney failure secondary to amyloidosis (a condition where amyloid proteins are deposited in organs and/or tissues). The mildest form, called Familial Cold Autoinflammatory Syndrome (FCAS), presents with cold-induced episodes of fever, rash and malaise. The incidence of CAPS is estimated to be 1:1,000,000 worldwide.

About Sobi™

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,500 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi's revenue amounted to SEK 14.2 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com.

For more information please contact:

Paula Treutiger, Head of Communication & Investor Relations
0733 666 599
paula.treutiger@sobi.com

Maria Kruse, Corporate Communication & Investor Relations
0767 248 830
maria.kruse@sobi.com