PRESS RELEASE

Stockholm, 20 November 2013

Sobi receives approval for Kineret® for treatment of rare disease CAPS

Swedish Orphan Biovitrum AB (publ) (Sobi) announced today that the European Commission (EC) has approved Kineret (anakinra) for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). The decision follows a positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in September 2013.

This approval was based on the outcome of a long-term safety and efficacy study in children and adults with the most severe form of CAPS called Neonatal-Onset Multisystem Inflammatory Disease (NOMID), or Chronic Infantile Neurologic Cutaneous and Arthritis syndrome (CINCA). The study was conducted at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), part of the National Institutes of Health (NIH) in Bethesda, MD, USA.

“We are happy about the approval from the European Commission today. The EC approval of Kineret for CAPS is a significant result from a long-term collaboration with the NIH and patient societies,” said Birgitte Volck, Senior Vice President and Chief Medical Officer. “CAPS is a group of rare inherited inflammatory disorders with symptoms involving fever, rash, joint and muscle pain, and fatigue which in the more severe cases are potentially life threatening. Kineret can really make a difference in the lives of these patients.”

Kineret is now approved for use in children aged 8 months and older who suffer from CAPS. In December 2012, Kineret became the first and only FDA-approved therapy for NOMID/CINCA. Sobi will provide Kineret for home treatment in a prefilled syringe with a graduated label to allow precise and flexible dosing in children and adults.

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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 Neurologic Cutaneous and Arthritis 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 Kineret (anakinra)

Kineret is a recombinant protein that blocks the biological activity of IL-1 by binding to the interleukin-1 type 1 receptor, expressed in a wide variety of tissues and organs. IL-1 is a key mediator of inflammation and driver of autoinflammatory diseases. Kineret is approved for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above. Kineret is also approved for treatment of the signs and symptoms of Rheumatoid Arthritis (RA) in combination with methotrexate, in adults with an inadequate response to methotrexate alone. In early 2013, Sobi announced that the US Food and Drug Administration (FDA) had approved Kineret for the treatment of children and adults with neonatal-onset multisystem inflammatory disease (NOMID), the most severe form of CAPS. Kineret thereby became the first and only FDA-approved therapy for NOMID (CAPS).

For more information on Kineret, see the Summary of Product Characteristics [November 2013].

About Sobi

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on inflammation and genetic diseases, with three late stage biological development projects within haemophilia and neonatology. We also market a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2012, Sobi had total revenues of SEK 1.9 billion (€ 215 M) and about 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

For more information – not for publication

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