

Stockholm, 19 November 2012

Sobi files to expand Kineret® label to include CAPS

Sobi (STO: SOBI) has filed an application for an EU Marketing Authorization with the European Medicines Agency (EMA) for Kineret® (anakinra) for the indication of cryopyrin associated periodic syndromes (CAPS).

The filing is based on positive safety and efficacy outcome data from a long-term treatment study in children and adults with neonatal-onset multisystem inflammatory disease (NOMID), the most severe form of CAPS. The EMA filing follows the filing for Kineret for NOMID with the US Food and Drug Administration (FDA) in July 2012, which has been granted priority review with an expected approval date of 25 December 2012.

“The filing of Kineret for CAPS and NOMID in the EU and the US respectively are important milestones on Sobi’s journey to increase our support for the pediatric rheumatology field as well as for the rare disease community as a whole,” said Dr. Geoffrey McDonough, CEO of Sobi. “In reaching these goals, we aim to provide an important treatment option to benefit patients affected by IL-1-related conditions.”

Commenting on Sobi’s decision to file, Dr. Marco Gattorno of Gaslini Children’s Hospital in Genova, Italy and Principal Investigator of the Eurofever Registry for Autoinflammatory Diseases, stated: “CAPS is a life-long, severely debilitating disease where patients suffer substantial pain and progressive reduction in their quality of life. We need to find these patients early and to provide demonstrated safe and effective treatment options to avoid disease progression leading to organ damage. Each patient is different, and the addition of new treatment alternatives would lead to increased flexibility and better opportunities for optimal treatment for all patients.”

About CAPS

Cryopyrin associated periodic syndromes (CAPS) consist of three rare, autosomal dominant autoinflammatory conditions of varying severity and oftentimes overlapping symptoms. At the milder end of the scale (FCAS), it is characterized by life-long, cold-induced inflammatory episodes of fever, rash and malaise. When of intermediate severity (Muckle Wells syndrome), it is typically associated with more intense and enduring flares and morbidity, including progressive hearing loss and kidney failure secondary to amyloidosis (a condition where amyloid proteins are abnormally deposited in organs and/or tissues). In the most severe form (NOMID/CINCA), it is associated with increased mortality and nearly continuous rash, fevers, chronic aseptic meningitis, sensorineural involvement, craniofacial abnormalities and bone lesions. The incidence of CAPS is estimated to be 1:1,000,000 worldwide.

CAPS is characterized by uncontrolled overproduction of IL-1 beta. IL-1 induces a number of inflammatory responses such as fever, pain sensitization, bone and cartilage destruction and acute plasma protein response.

About Kineret (anakinra)

Kineret is a recombinant protein drug approved for the treatment of rheumatoid arthritis (RA). Kineret 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 in both adults and children. For more information on Kineret see the Summary of Product Characteristics.

For further information, please contact:

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About Swedish Orphan Biovitrum (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 hemophilia and neonatology. We also market more than 40 products for companies in the specialty and rare disease space. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2011, Sobi had total revenues of SEK 1.9 billion (€ 214 M) and about 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.