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## Sobi files for NOMID indication for Kineret in US

Sobi has filed an application for Kineret® (anakinra) for the indication of neonatal-onset multisystem inflammatory disease (NOMID) with the Federal Drug Administration (FDA) in the US. The filing is made under an Orphan Drug Designation for the indication cryopyrin associated periodic syndromes (CAPS), which was granted in 2010. If the application is granted priority review, Sobi expects a review period of 6-8 months.

The basis for the filing is a clinical trial initiated and conducted by Principal Investigator Dr Raphaela Goldbach-Mansky at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at NIH in Bethesda, MD. The trial which includes a majority of NOMID patients in the US has gathered extensive long-term treatment data.

“We are delighted to be taking this important step for infants, children and adults with NOMID” said Sobi CEO Geoffrey McDonough. “This is the outcome of a strong collaboration with the NIH and reflects our shared commitment to the orphan drug community and to supporting the pediatric rheumatology field.”

“The awareness and understanding of NOMID has increased significantly in the last couple of years”, said Mrs. Karen Durrant, President of The NOMID Alliance - a non-profit organization for patients with CAPS and other autoinflammatory diseases. “However, there is still an unmet medical need for these severely ill patients and an FDA approved therapy for this drug would greatly facilitate access to reimbursed medication.”

### **About CAPS and NOMID**

Cryopyrin associated periodic syndromes (CAPS) is a rare, autosomal dominant disease consisting of three autoinflammatory conditions of varying severity and oftentimes overlapping symptoms. At the milder end it is characterized by life-long, cold-induced inflammatory episodes of fever, rash and malaise. When of intermediate severity, 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), it is associated with increased mortality and nearly continuous fevers, rash, chronic aseptic meningitis, sensorineural involvement, craniofacial abnormalities, and exuberant bone lesions. The incidence of NOMID is estimated to be less than 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**

Kineret, which is part of Sobi's Core Products business line, 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, which is 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.

Healthcare professionals should refer to and rely upon the PDR (Physician's Desk Reference) or the corresponding national labeling texts.

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**Swedish Orphan Biovitrum (Sobi)**

Sobi is a leading integrated biopharmaceutical company dedicated to bringing innovative therapies and services to improve the health of rare disease patients and their families. The product portfolio comprises about 45 marketed products as well as projects in the late clinical phase. Key therapeutic areas are Inflammation and Genetics & Metabolism. In 2011, Sobi had revenues of SEK 1.9 billion and around 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at [www.sobi.com](http://www.sobi.com).