

## Swedish Orphan Biovitrum's Kineret® has Received Orphan Drug Designation in the USA

**Stockholm, Sweden – August 26, 2010 - Swedish Orphan Biovitrum (STO: SOBI) today announced that the US FDA Office of Orphan Products Development (OOPD) has granted orphan drug designation (ODD) to Kineret® for the treatment of cryopyrin-associated periodic syndromes (CAPS).**

CAPS is a rare autoinflammatory condition with very severe symptoms and is potentially lethal. CAPS is characterized by excessive production of the endogenous inflammatory protein interleukin 1 $\beta$  (IL-1 $\beta$ ). Kineret® is a recombinant version of the naturally occurring IL-1 receptor antagonist which blocks the IL-1 receptor.

"The orphan drug designation (ODD) is an important step in our efforts to document Kineret for the severe and very debilitating disease CAPS. An ODD gives advantages in FDA assistance, user-fee benefits and, after orphan drug registration, seven years of market exclusivity. This will help us in our efforts to offer this potentially very valuable product to CAPS patients with high unmet medical needs." said Peter Edman, Ph.D., Chief Scientific Officer of Swedish Orphan Biovitrum.

### **About cryopyrin-associated periodic syndromes (CAPS)**

Cryopyrin-associated periodic syndromes are members of a family of autoinflammatory diseases. 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/CINCA) is associated with high mortality and nearly continuous fevers, rash, chronic aseptic meningitis, sensorineural involvement, craniofacial abnormalities, and exuberant bone lesions. The incidence is estimated to be approximately 1:1,000,000 worldwide, but could be underestimated.

CAPS is characterized by excessive or uncontrolled IL-1 $\beta$  production. IL-1 induces a number of inflammatory responses such as fever, pain sensitization, bone and cartilage destruction and acute plasma protein response. Approximately 20% of untreated children with NOMID/CINCA syndrome die before reaching adulthood.

### **About Kineret® (anakinra)**

In December 2008, Swedish Orphan Biovitrum obtained from Amgen the global exclusive rights to Kineret® for rheumatoid arthritis as currently indicated in its label. In November 2009, the agreement regarding Swedish Orphan Biovitrum's Kineret® license was expanded to include certain orphan indications. Information about Kineret® can be found at the following site: <http://www.kineretrx.com/>  
Healthcare professionals should refer to and rely upon the PDR (Physician's Desk Reference) or the corresponding national labeling texts.

**About Swedish Orphan Biovitrum**

Swedish Orphan Biovitrum is a Swedish based niche specialty pharmaceutical company with an international market presence. The company is focused on providing and developing specialist pharmaceuticals for rare disease patients with high medical needs. The portfolio consists of about 60 marketed products and an emerging late stage clinical development pipe-line. Our focus areas are: hemophilia, inflammation/autoimmune diseases, fat malabsorption, cancer supportive care and inherited metabolic disorders. Swedish Orphan Biovitrum had pro-forma revenues 2009e of about 2 BSEK and approximately 500 employees. The head office is located in Sweden and the share (STO: SOBI) is listed on NASDAQ OMX Stockholm. For more information please visit [www.sobi.com](http://www.sobi.com).

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*Swedish Orphan Biovitrum may be required to disclose the information provided herein pursuant to the Swedish Securities Markets Act. The information was provided for public release on August 26, 2010 at 8:30 a.m. CET.*