

## PRESS RELEASE

Stockholm, 11 June, 2013



### **Sobi gets FDA approval to manufacture substance for Kineret® with partner Boehringer Ingelheim**

Swedish Orphan Biovitrum AB (publ) (Sobi) today announced receipt of approval from the Food and Drug Administration (FDA) for the manufacture of drug substance for Kineret® (anakinra) at Boehringer Ingelheim's microbial site in Vienna, Austria. The approval allows for distribution of Kineret in the US, and comes as the result of a Supplemental Biologics License Application (sBLA) filed with the FDA in February 2013.

"We are very pleased that the FDA has approved our technology transfer of Kineret manufacturing from Amgen to Boehringer Ingelheim", said Geoffrey McDonough, CEO and President of Sobi. "This completes the process and establishes our supply chain for the long term supply of Kineret."

"Boehringer Ingelheim is excited about this important milestone for Kineret®", stated Christian Eckermann, Head of Boehringer Ingelheim Biopharmaceuticals site Austria. "We are happy to continue the long term partnership with Sobi by supplying Kineret® also to the US market."

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#### **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 hemophilia 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](http://www.sobi.com)

#### **About Kineret® (anakinra)**

Kineret is a recombinant protein drug approved for the treatment of children and adults with NOMID, and the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs). 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 Prescribing Information. ([www.kineretrx.com](http://www.kineretrx.com))

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### About Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies with net sales of about 14.7 billion Euros in 2012. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel medications of high therapeutic value for human and veterinary medicine.

All activities of the biopharmaceutical contract manufacturing are performed within the Boehringer Ingelheim Biopharmaceuticals GmbH, headquartered in Ingelheim, Germany and are represented by its new brand Boehringer Ingelheim BioXcellence™. As a leading biopharmaceutical contract manufacturer with more than 35 years of experience - the company has brought more than 20 biopharmaceutical products to market. Boehringer Ingelheim BioXcellence™ offers tailor-made contract development and manufacturing services to the biopharmaceutical industry, providing the entire production technology chain from DNA to fill and finish under one roof at its facilities in Biberach (Germany), Vienna (Austria) and Fremont (USA). Boehringer Ingelheim BioXcellence™ can secure product supply throughout the entire product lifecycle-transferring customer projects at any stage, delivering to almost any scale and thereby makes outsourcing easy.

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