

## PRESS RELEASE

Stockholm, 9 September 2013



### Sobi acquires full rights for Kineret® and additional clinical data for Kepivance® from Amgen

Swedish Orphan Biovitrum AB (publ) (Sobi) announced today that they have acquired the full rights to develop and commercialize Kineret (anakinra) from American biotechnology company Amgen for all therapeutic indications. The revised agreement builds on the previous agreement that gave Sobi rights for Kineret within the field of Rheumatoid arthritis (RA) and four orphan drug indications, including Cryopyrin Associated Periodic Syndrome (CAPS).

Sobi also acquired the right to additional data for Kepivance allowing the company to explore a potential new therapeutic indication based on two completed phase III trials performed by Amgen. The two randomized double blind placebo controlled trials, involving over 400 patients, demonstrate the potential for Kepivance to reduce the incidence of severe oral mucositis in patients undergoing treatment for advanced head and neck cancer.

"This amendment to our existing agreement builds on a strong partnership with Amgen," said Geoffrey McDonough, CEO and President for Sobi. "Kineret is already an important product for Sobi and this amended agreement offers the potential for Sobi to explore its application to new indications, and the clinical trial data for Kepivance may allow us to make this therapy available to a substantially larger group of patients in the future."

Under the terms of the amended agreement, Sobi and Amgen have restructured the financial terms of their original deal to accommodate the acquisition of additional rights and data.

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### About Kineret (anakinra)

Kineret is a recombinant protein drug approved for, and the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate, in patients 18 years of age or older who have had an inadequate response to methotrexate alone. 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. For more information on Kineret see the Prescribing Information. ([www.kineretrx.com](http://www.kineretrx.com))

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).

### About Kepivance

Kepivance is indicated to decrease the incidence, duration and severity of severe mucositis in adult patients with haematological malignancies receiving myeloablative radiochemotherapy associated with a high incidence of severe mucositis and requiring autologous haematopoietic stem cell support. Information about Kepivance can be found on: [www.kepivance.com](http://www.kepivance.com)

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

### For more information – not for publication

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