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# Sobi and Savient Pharmaceuticals Announce Co-Promotion Agreement for Kineret® (anakinra) in the U.S.

Stockholm, Sweden / Bridgewater, New Jersey, February 19, 2013 - Sobi (STO: Sobi) and Savient Pharmaceuticals, Inc. (NASDAQ: SVNT) announced today that they have entered into an agreement for the co-promotion of Kineret® (anakinra) in the U.S.

Kineret, a recombinant IL-1 receptor antagonist, is a treatment for rheumatoid arthritis (RA) and indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active RA in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs). Kineret is also indicated in the U.S. for the treatment of children and adults with the severe form of Cryopyrin-Associated Periodic Syndromes (CAPS) called Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

"Savient's organization will enhance our support for Kineret in the United States," said Alan Raffensperger, Chief Operating Officer of Sobi. "The collaboration will expand our reach to U.S. physicians who treat patients suffering from rheumatoid arthritis and augment our own ability to directly support the pediatric community. Kineret is an important treatment for these patient groups".

Savient is a specialty biopharmaceutical company that has developed and commercialized KRYSTEXXA® (pegloticase) for the treatment of refractory chronic gout in the U.S. Savient's specialized sales force has strong, established relationships with rheumatologists in the U.S., making Savient an excellent partner for Sobi.

"We are pleased to announce the collaboration with Sobi," said Lou Ferrari, President and Chief Executive Officer of Savient. "Kineret complements the strategic direction and focus of Savient, as we continue to build upon our existing relationships with rheumatologists and patients while marketing our own product, KRYSTEXXA. We look forward to working with Sobi to make Kineret more widely available to patients with rheumatoid arthritis."

Under the terms of the agreement, Sobi has granted to Savient the exclusive right to co-promote the sale of Kineret with Sobi in the U.S. Savient will market and promote Kineret beginning April 1, 2013. Sobi will remain responsible for all Kineret commercial drug manufacturing, supply, safety, and regulatory activities.

## About Swedish Orphan Biovitrum AB (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 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 2011, Sobi had total revenues of SEK 1.9 billion ( $\epsilon$  214 M) and about 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at <a href="https://www.sobi.com">www.sobi.com</a>.

## **About Rheumatoid Arthritis**

Rheumatoid arthritis is a common systemic disease that affects connective tissue. Arthritis is the dominant clinical manifestation, involving many joints, especially those of the hands and feet. The course is variable, but often chronic and progressive, leading to deformity and disability. Patients with rheumatoid arthritis produce excess amounts of inflammatory cytokines, among them Interleukin-1. This leads to harmful effects such as swelling and tissue damage.

## **About CAPS and NOMID**

Cryopyrin associated periodic syndromes (CAPS) are a group of rare inherited autoinflammatory diseases caused by autosomal dominant mutations in a gene called NLRP3. CAPS is characterized by uncontrolled overproduction of IL-1beta. IL-1 induces a number of inflammatory responses such as fever, pain sensitization, bone and cartilage destruction and acute plasma protein responses. In the most severe form NOMID, also called chronic infantile neurologic cutaneous and arthritis syndrome (CINCA) in Europe, it is associated with increased mortality and fever, rash, chronic aseptic meningitis, sensorineural hearing loss, craniofacial abnormalities, and bone lesions. When of intermediate severity, the disease is typically associated with episodic, intense and enduring flares and morbidity, including progressive hearing loss and kidney failure secondary to amyloidosis (a condition where amyloid proteins are deposited in organs and/or tissues). The mildest form presents with cold-induced episodes of fever, rash and malaise. The incidence of CAPS is estimated to be 1:1,000,000 worldwide.

#### About Kineret (anakinra)

Kineret<sup>®</sup> 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. (<a href="https://www.kineretrx.com">www.kineretrx.com</a>).

## **Kineret - Important Safety Information**

Do not take Kineret if you have an allergy to:

- proteins made from bacterial cells (E. coli). Ask your healthcare provider if you are not sure.
- any of the ingredients in Kineret. See the end of the patient leaflet for a complete list of ingredients in Kineret. Before taking Kineret, tell your healthcare provider if you:
- have an infection, a history of infections that keep coming back or other problems that can increase your risk of infections.
- have an allergy to rubber or latex. The needle cover on the prefilled syringe contains latex. Do not handle the needle cover if you are allergic to latex.
- have kidney problems.
- are scheduled to receive any vaccines. People using Kineret should not receive live vaccines.
- are pregnant or plan to become pregnant. It is not known if Kineret will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Kineret passes into your breast milk. You and your healthcare provider should decide if you will take Kineret or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Tell your healthcare provider if you take other medicines that affect your immune system. Especially tell your healthcare provider if you use: ENBREL® (etanercept), HUMIRA® (adalimumab), or REMICADE® (infliximab).

Kineret may cause serious side effects, including:

- serious infections. Kineret may lower your ability to fight infections. During treatment with Kineret, call your healthcare provider right away if you get an infection, have any sign of an infection including a fever, chills, or have any open sores on your body.
- low white blood cell count (neutropenia). Kineret may cause you to have a lower number of certain white cells (neutrophils). Neutrophils are important in fighting infections. You should have blood tests before starting treatment with Kineret, then monthly for 3 months. After the first 3 months you should have your blood tested every 3 months for up to 1 year.
- allergic reactions. Stop using Kineret and call your healthcare provider or get emergency help right away if you have any of these symptoms of an allergic reaction: swelling of your face, lips, mouth or tongue; trouble breathing; wheezing; severe itching; skin rash, redness, or swelling outside of the injection site area; dizziness or fainting; fast heartbeat or pounding in your chest (tachycardia); or sweating.

The most common side effects of Kineret include:

• injection site skin reactions, including redness, swelling, bruising, itching, and stinging. Most injection site reactions are mild, occur early during treatment, and last about 2-4 weeks. Injection site reactions have been observed less frequently in people with NOMID.

- headache
- nausea and vomiting
- joint pain
- fever
- feeling like you have the flu
- sore throat or runny nose
- sinus infection
- pain in your stomach area

These are not all of the possible side effects of Kineret. Tell your healthcare provider if you have any side effect that bothers you or does not go away. For more information ask your healthcare provider or pharmacist.

Enbrel® is a registered trademark of Immunex Corporation, Thousand Oaks, Ca. Remicade® is a registered trademark of Centocor, Inc., Malvern, Pa. Humira® is a registered trademark of Abbott Laboratories, Abbot Park, IL.

## **Forward-Looking Statements**

The information above includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of research programs and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing research programs that may affect Swedish Orphan Biovitrum's results. The information above has been published pursuant to the Swedish Securities Market Act and/or the Financial Instruments Trading Act. The information was released for public distribution on 19 February, 2013 at 2:30 p.m. CET.

#### About Savient Pharmaceuticals, Inc.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing and commercializing KRYSTEXXA® (pegloticase) for the treatment of chronic gout in adult patients who do not respond to conventional therapy. Savient has exclusively licensed worldwide rights to the technology related to KRYSTEXXA and its uses from Duke University ("Duke") and Mountain View Pharmaceuticals, Inc. ("MVP"). Duke developed the recombinant uricase enzyme and MVP developed the PEGylation technology used in the manufacture of KRYSTEXXA. MVP and Duke have been granted US and foreign patents disclosing and claiming the licensed technology and, in addition, Savient owns or co-owns US and foreign patents and patent applications, which collectively form a broad portfolio of patents covering the composition, manufacture and methods of use and administration of KRYSTEXXA. Savient also supplies Oxandrin® (oxandrolone tablets, USP) CIII in the US For more information, please visit the Company's website at <a href="www.savient.com">www.savient.com</a>.

## **Forward-Looking Statements**

All statements other than statements of historical facts included in this press release are forward-looking statements that are subject to certain risks, trends and uncertainties that could cause actual results and achievements to differ materially from those expressed in such statements. These risks, trends and uncertainties are in some instances beyond our control. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "will" and other similar expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding the co-promotion arrangement for Kineret, our commercialization of KRYSTEXXA and our relationship with rheumatologists are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our assessment and interpretation of the currently available data and information, current expectations, assumptions, estimates and projections about our business and the biopharmaceutical and specialty pharmaceutical industries in which we operate. Important factors that may affect our ability to achieve the matters addressed in these forward-looking statements include, but are not limited to, our ability to copromote Kineret and continue our commercialization of KRYSTEXXA; our ability to retain the personnel; competition from existing therapies and therapies that are currently under development; whether we are able to obtain financing, if needed; economic, political and other risks associated with foreign operations; risks of maintaining protection for our intellectual property; risks of an adverse determination in intellectual property litigation; and risks associated with stringent government regulation of the biopharmaceutical industry and other important factors and other important factors set forth more fully in our reports filed with the Securities and Exchange Commission, to which investors are referred for further information. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements, which speak only as of the date of publication of this press release. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not have a policy of updating or revising forward-looking statements and, except as required by law, assume no obligation to update any forward-looking statements.