# PRESS RELEASE

Stockholm, 25 March 2014

**Cometriq® approved in Europe for the treatment of progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma.**

Swedish Orphan Biovitrum AB's (publ) (Sobi) partner Exelixis, Inc. (NASDAQ:EXEL) today announced that the European Commission has approved Cometriq® (cabozantinib) for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma (MTC). The European Commission granted conditional marketing authorisation following a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) issued in December 2013. Similar to another drug approved in this setting, the approved indication states that for patients in whom Rearranged during Transfection (RET) mutation status is not known or is negative, a possible lower benefit should be taken into account before individual treatment decisions.

"We're pleased that physicians in the European Union who treat patients with progressive, unresectable locally advanced or metastatic MTC now have a new treatment option in Cometriq," said Anders Edvell, MD, PhD, Vice President Sobi Partner Products.

The Committee for Orphan Medicinal Products (COMP) also reviewed the designation for Cometriq (cabozantinib) as an orphan medicinal product for the treatment of MTC, and recommended maintenance of orphan drug designation at the time of marketing authorisation.

The U.S. Food and Drug Administration approved Cometriq for the treatment of progressive, metastatic MTC in the United States on November 29, 2012. The approvals of Cometriq in both the United States and the European Union were based on data from EXAM, the international, multi-centre, randomised double-blinded controlled phase 3 clinical trial conducted in 330 patients with progressive, unresectable locally advanced or metastatic MTC, in which cabozantinib met its primary efficacy endpoint of improving progression-free survival (PFS) as compared to placebo.

Pursuant to the terms of a commercialization and distribution agreement between Exelixis and Sobi signed in February 2013, Sobi will support the commercialisation of Cometriq in the European Union for the approved indication through the end of 2015.

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**About Cabozantinib**

Cabozantinib inhibits the activity of tyrosine kinases including RET, MET and VEGFRs. These receptor tyrosine kinases are involved in both normal cellular function and in pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and maintenance of the tumor microenvironment.

**Swedish Orphan Biovitrum AB**
Postal address SE-112 76 Stockholm, Sweden
Phone: +46 697 20 00 Fax +46 697 20 00 www.sobi.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 2013, Sobi had total revenues of SEK 2.2 billion (€253 M) and about 550 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

**About Sobi Partner Products**

Sobi Partner Products (SPP) is a business unit within Sobi which offers a unique commercial platform for partners with niche and specialty products. SPP provides extensive knowledge and local experience through our direct presence across EU, Eastern Europe, Russia, Middle East and North Africa. We apply an integrated commercial, medical, and market access approach to products which address important unmet needs, spanning from named patient use (NPU) programs, through to reimbursement and full commercialization, primarily in the Centre of Expertise setting.

**For more information please contact**

Media relations
Oskar Bosson, Head of Communications
T: +46 70 410 71 80
oskar.bosson@sobi.com

Investor relations
Jörgen Winroth, Vice President, Head of Investor Relations
T: +1 347-224-0819, +1 212-579-0506, +46 8 697 2135
jorgen.winroth@sobi.com