Exelixis and Swedish Orphan Biovitrum AB (Sobi) Extend and Restructure Distribution Agreement for COMETRIQ® for Medullary Thyroid Cancer

January 7, 2015

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 7, 2015-- Exelixis, Inc. (NASDAQ:EXEL) today announced that it has extended and restructured its agreement with Swedish Orphan Biovitrum AB (Sobi) to support the distribution and commercialization of COMETRIQ® (cabozantinib) for progressive, unresectable, locally advanced or metastatic medullary thyroid cancer (MTC) in the European Union (EU), Switzerland, Norway, Russia, and Turkey. The agreement, which was established in February 2013 and due to expire on December 31, 2015, will now extend to December 31, 2019. Moreover, the payment structure of the partnership will transition from fixed fees paid by Exelixis to Sobi to support initial build out of COMETRIQ European commercial infrastructure to a sales margin-based approach. Exelixis continues to maintain commercial rights for all other potential cabozantinib oncology indications on a global basis.

“Our amended agreement with Sobi will continue to allow Exelixis to provide COMETRIQ to MTC patients outside the United States,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “Over the course of this coming year, we anticipate reaching several key milestones for the company, including receipt of top-line data from the METEOR phase 3 trial of cabozantinib in metastatic renal cell carcinoma in the second quarter, and regulatory progress with our partnered compound cobimetinib for metastatic melanoma in both the United States and European Union.”

“We are very pleased to extend the agreement with Exelixis and proud to support access to COMETRIQ in Europe. The evolution of our partnership with Exelixis will continue to bring significant value to patients,” said Anders Edvell, Vice President and Head of Sobi Partner Products at Sobi.

Sobi exclusively markets, sells, and distributes COMETRIQ for its MTC indication in the covered territory of the European Union, Switzerland, Norway, Russia, and Turkey. In parts of the territory where COMETRIQ is not approved, Sobi administers a Named Patient Use program. Exelixis is responsible for regulatory approvals in the covered territory, and the company retains the ability to terminate the agreement at will at any time upon payment of certain pre-determined fees.

About Cabozantinib

Cabozantinib inhibits the activity of tyrosine kinases including MET, VEGFRs and RET. 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.

COMETRIQ® (cabozantinib) is currently approved by the U.S. Food and Drug Administration for the treatment of progressive, metastatic medullary thyroid cancer (MTC).

The European Commission granted COMETRIQ conditional approval for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC. 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.

Important Safety Information, including Boxed WARNINGS

WARNING: **PERFORATIONS AND FISTULAS**, **and HEMORRHAGE**

- **Serious and sometimes fatal gastrointestinal perforations and fistulas occur in COMETRIQ-treated patients.**
- **Severe and sometimes fatal hemorrhage occurs in COMETRIQ-treated patients.**
- COMETRIQ treatment results in an increase in thrombotic events, such as heart attacks.
- Wound complications have been reported with COMETRIQ.
- COMETRIQ treatment results in an increase in hypertension.
- Osteonecrosis of the jaw has been observed in COMETRIQ-treated patients.
- Palmar-Plantar Erythrodysesthesia Syndrome (PPES) occurs in patients treated with COMETRIQ.
- The kidneys can be adversely affected by COMETRIQ. Proteinuria and nephrotic syndrome have been reported in patients receiving COMETRIQ.
- Reversible Posterior Leukoencephalopathy Syndrome has been observed with COMETRIQ.
- Avoid administration of COMETRIQ with agents that are strong CYP3A4 inducers or inhibitors.
- COMETRIQ is not recommended for use in patients with moderate or severe hepatic impairment.
- COMETRIQ can cause fetal harm when administered to a pregnant woman.

Adverse Reactions – The most commonly reported adverse drug reactions (≥25%) are diarrhea, stomatitis, palmar-plantar erythrodysesthesia syndrome (PPES), decreased weight, decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain,

and constipation. The most common laboratory abnormalities (≥25%) are increased AST, increased ALT, lymphopenia, increased alkaline phosphatase, hypocalcemia, neutropenia, thrombocytopenia, hypophosphatemia, and hyperbilirubinemia.

Please see full U.S. prescribing information, including Boxed WARNINGS, at www.COMETRIQ.com/downloads/Cometriq_Full_Prescribing_Information.pdf. Please refer to the full European Summary of Product Characteristics for full European Union prescribing information, including contraindication, special warnings and precautions for use at www.sobi.com once posted.

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, working from named patient use (NPU) programs through to reimbursement and commercialization, primarily in the Centre of Expertise setting. The key SPP therapeutic areas are Oncology, Haematology, Infectious Diseases, and Emergency Medicines & Antidotes.

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 two late stage biological development projects within Haemophilia. 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 Exelixis

Exelixis, Inc. is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its development and commercialization efforts primarily on COMETRIQ® (cabozantinib), its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a highly selective inhibitor of MEK, is being evaluated by Roche and Genentech (a member of the Roche Group) in a broad development program under a collaboration with Exelixis. For more information, please visit the company's web site at www.exelixis.com.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements by Exelixis, including, without limitation, statements related to: the clinical, therapeutic and commercial potential of COMETRIQ; the clinical and commercial opportunity for COMETRIQ in MTC in the EU and potentially other countries; the companies' plan for Sobi to provide the referenced distribution and commercialization services for COMETRIQ for the stated duration; commercial rights to cabozantinib for other oncology indications and their potential value; Exelixis' belief that the referenced agreement will enable Exelixis to continue to make COMETRIQ available to MTC patients outside the US; the performance by the parties under the referenced agreement; the expected benefits to each party arising under the referenced agreement; and Exelexis' expectation to reach key milestones in 2015, including METEOR top-line data in RCC in the second quarter and regulatory progress with cobimetinib for metastatic melanoma in the US and EU. Words such as "extend," "support," "will," "transition," "continue," "maintain," "allow," "potential," "provide," "anticipate," "reaching," "look forward," "progress," "become," "retain," "can," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the degree of market acceptance of COMETRIQ; the extent to which coverage and reimbursement for COMETRIQ will be available from third-party payors; risks and uncertainties related to regulatory review and approval processes and Exelixis' and Sobi's compliance with applicable legal and regulatory requirements, including healthcare fraud and abuse laws; Exelixis' dependence on Sobi under the referenced agreement; market competition; risks related to the potential failure of cobimetinib or cabozantinib to demonstrate safety and efficacy in clinical testing; the availability of data at the expected times; the clinical, therapeutic and commercial value of cobimetinib and cabozantinib; the general sufficiency of Exelixis' capital and other resources and the specific risk of unforeseen expenses that could diminish Exelixis' financial ability to support its operations through the release of top-line results from METEOR; the uncertain timing and level of expenses associated with the development of cabozantinib; changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 4, 2014, and Exelixis' other filings with the SEC. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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Exelixis, Inc.
Susan Hubbard, 650-837-8194
Investor Relations & Corporate Communications
shubbard@exelixis.com