Exelixis Selects Swedish Orphan Biovitrum AB as COMETRIQ™ European Distributor for Medullary Thyroid Cancer

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SOUTH SAN FRANCISCO, Calif. & STOCKHOLM--(BUSINESS WIRE)--Feb. 21, 2013-- Exelixis, Inc. (NASDAQ:EXEL) and Swedish Orphan Biovitrum (Sobi) (STO: SOBI) today announced that they have entered into a three-year agreement to support the distribution and commercialization of COMETRIQ™ (cabozantinib) for metastatic medullary thyroid cancer (MTC) in the European Union (EU) and potentially other countries. No other indication is covered by this agreement, and Exelixis maintains full commercial rights for COMETRIQ in MTC outside the covered territory and for all other indications on a global basis. On November 29, 2012, Exelixis announced that the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for COMETRIQ for the proposed indication of treatment of progressive, unresectable, locally advanced, or metastatic MTC.

“We are pleased to be working with Sobi to distribute and commercialize COMETRIQ for MTC in the EU, while at the same time maintaining commercial rights for all other oncology indications on a global basis,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “By contracting with Sobi for distribution and commercialization services, we believe we will be able to realize the full value of the MTC opportunity in Europe and potentially other regions without the need for a large-scale investment in sales and marketing infrastructure. This strategy is consistent with our commitment to match our commercialization investments with the potential value of each opportunity. We look forward to working with Sobi, which has proven sales and marketing expertise in Europe, to make COMETRIQ available under a Named Patient Use (NPU) program and then more broadly assuming EMA approval.”

“COMETRIQ is an important potential new treatment option for patients with metastatic MTC,” said Anders Edvell, Vice President and Head of Partner Products at Sobi. “We look forward to leveraging our years of specialized expertise in these markets to support the COMETRIQ NPU program and, upon EMA approval, its commercial development in MTC.”

Under the terms of the agreement, Exelixis will continue to be responsible for regulatory approvals in the covered territory. Sobi will serve as the exclusive distributor of COMETRIQ in the covered territory where applicable for NPU requests, and will, if approved by the EMA, promote, market, and sell COMETRIQ for MTC in the covered territory. Exelixis’ payments to Sobi include certain pre-determined fixed fees as well as potential performance based milestones related to the commercialization of the product in the covered territory. Exelixis will book revenues based on product sold to Sobi. Exelixis has the ability to terminate the agreement at will at any time upon payment of certain pre-determined fees.

About Named Patient Use (NPU) Programs

A named patient use (NPU) program provides access to unapproved drugs for a single patient or group of patients in a particular country. Products offered through NPU programs can be investigational (e.g. still in clinical studies) or approved in one country but not yet approved in the patient’s home country. Regulations governing NPU programs vary by country but companies offering products through NPU can sometimes charge for the product being administered.

About COMETRIQ™

COMETRIQ (cabozantinib) inhibits the activity of tyrosine kinases including RET, MET and VEGFR2. 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. Exelixis received approval by the FDA to market COMETRIQ in the United States for the treatment of progressive, metastatic MTC in November 2012. Please see important safety information below, and the full prescribing information, including Boxed Warning, for COMETRIQ at www.exelixis.com or www.COMETRIQ.com.

COMETRIQ™ Important Safety Information, including Boxed Warning

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 (PPE) Syndrome 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.

- 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.

Drug Interactions – COMETRIQ is a CYP3A4 substrate. Co-administration of strong CYP3A4 inhibitors can increase cabozantinib exposure. Chronic co-administration of strong CYP3A4 inducers can reduce cabozantinib exposure.

For full prescribing information, including Boxed Warning, please visit www.exelixis.com or www.COMETRIQ.com.

About Exelixis

Exelixis, Inc. is a biotechnology company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its proprietary resources and development efforts exclusively on COMETRIQ™ (cabozantinib)Exelixis has also established a portfolio of other novel compounds that it believes have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations. For more information, please visit the company's web site at www.exelixis.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, 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, Hematology, 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 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 480 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available atwww.sobi.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; Exelixis' belief that the referenced agreement will enable Exelixis to realize the full value of the MTC opportunity in Europe and potentially other regions without the need for a large-scale investment in sales and marketing infrastructure; Exelixis' commitment to match commercialization investments with the potential value of each opportunity; the referenced review by the EMA of the MAA, and the potential approval of the MAA; the plan for Exelixis to continue to be responsible for regulatory approvals in the covered territory; the performance by the parties under the referenced agreement; the expected benefits to each party arising under the referenced agreement; and Exelixis' expectation for booking revenues under the referenced agreement. Words such as "support," "maintains," "review," "proposed," "believe," "will," "realize," "opportunity," "potential," "strategy," "look forward," "assuming," "continue," "ability," "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 risk that unanticipated developments could delay or prevent the launch, commercialization, manufacturing, distribution and availability of COMETRIQ in the covered territory; 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 Exelixis' compliance with applicable regulatory requirements, including healthcare fraud and abuse laws; Exelixis' dependence on Sobi under the referenced agreement; market competition; the uncertainty of the regulatory approval process; and changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' annual report on Form 10-K for the fiscal year ended December 28, 2012, filed with the Securities and Exchange Commission (SEC) on February 21, 2013, 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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