# Exelixis Receives Approval for COMETRIQ® (Cabozantinib) in the European Union for Treatment of Progressive, Unresectable Locally Advanced or Metastatic Medullary Thyroid Carcinoma

March 25, 2014

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 25, 2014-- 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 authorization 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 are pleased that physicians who treat patients with progressive, unresectable locally advanced or metastatic MTC in the European Union will now have COMETRIQ as a treatment option,” said Michael Morrissey, Ph.D., president and chief executive officer of Exelixis. “This patient population is in need of new therapies, and we believe that COMETRIQ provides an important new option for these patients.”

Additionally, the Committee for Orphan Medicinal Products (COMP) during its January 2014 meeting reviewed the designation for COMETRIQ (cabozantinib) as an orphan medicinal product for the treatment of medullary thyroid carcinoma and recommended maintenance of orphan drug designation at the time of marketing authorization.

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-center, randomized 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. Please see Important Safety Information for COMETRIQ, including Boxed Warnings, below.

Pursuant to the terms of a commercialization and distribution agreement between Exelixis and Swedish Orphan Biovitrum (Sobi) signed in February 2013, Sobi will support the commercialization of COMETRIQ in the European Union for the approved indication through the end of 2015.

**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.

**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 Exelixis**

Exelixis 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.

**Forward-Looking Statements**

This press release contains forward-looking statements, including, without limitation, statements related to: the referenced conditional marketing authorization for COMETRIQ® (cabozantinib) in the European Union; the belief that COMETRIQ provides an important new option for patients in the European Union with progressive, unresectable locally advanced or metastatic MTC; the commercial availability of COMETRIQ in the European Union and the plan for Sobi to support the product's commercialization in the European Union; and the continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib. Words such as "conditional," "should," "will," "believe," "new," "option," "support," "potential," 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; 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' ability to maintain compliance with the requirements for conditional marketing authorization in the European Union; risks and uncertainties related to Exelixis' compliance with other applicable regulatory requirements, including healthcare fraud and abuse laws and post-marketing requirements; Exelixis' dependence on third-party vendors; market competition; the uncertainty of regulatory approval processes; 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 27, 2013, filed with the Securities and Exchange Commission (SEC) on February 20, 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.



Source: Exelixis, Inc.

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