COMETRIQ® (cabozantinib) Receives Positive Opinion from European Committee for Medicinal Products for Human Use for Progressive, Unresectable Locally Advanced or Metastatic Medullary Thyroid Carcinoma

December 19, 2013

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 19, 2013-- Exelixis, Inc. (NASDAQ:EXEL) today announced that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion of the Marketing Authorization Application (MAA) for COMETRIQ® (cabozantinib) for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma (MTC). The proposed indication also 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. The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union.

The MAA upon which the CHMP issued its opinion contains 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. This trial also served as the basis for Exelixis' New Drug Application with the U.S. Food and Drug Administration, which approved COMETRIQ for the treatment of progressive, metastatic MTC in the United States on November 29, 2012. Please see Important Safety Information for COMETRIQ, including Boxed WARNINGS, below.

"The positive opinion issued by the CHMP marks an important milestone for Exelixis and the next step in making COMETRIQ commercially available in the European Union," said Michael Morrissey, Ph.D., president and chief executive officer of Exelixis. "We are looking forward to working with the European Commission to complete the review process for COMETRIQ's proposed indication as a treatment for progressive, unresectable locally advanced or metastatic MTC."

If the European Commission approves COMETRIQ based on the CHMP's positive opinion, Swedish Orphan Biovitrum (Sobi) would support the product's commercialization in the European Union for the approved indication through the end of 2015, pursuant to the terms of a commercialization and distribution agreement between Exelixis and Sobi signed in January 2013.

About Cabozantinib

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

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 (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.
- 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 prescribing information, including Boxed WARNINGS, at www.COMETRIQ.com/downloads/Cometriq_Full_Prescribing_Information.pdf

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 review by the European Commission of the CHMP's referenced positive opinion and of the referenced MAA for COMETRIQ® (cabozantinib); Exelixis' plan to work with the European Commission to complete the review process for COMETRIQ's proposed indication as a treatment for progressive, unresectable locally advanced or metastatic MTC; the potential approval by the European Commission of the proposed indication of COMETRIQ for the treatment of progressive, unresectable locally advanced or metastatic MTC; the potential 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 "should," "will," "milestone," "next step," "available," "looking forward," "working," "complete," "review," "proposed," "would," "support," "believe," "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 uncertainty of the regulatory approval processes; the sufficiency of Exelixis' capital and other resources; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; the uncertain timing and level of expenses associated with the development of cabozantinib; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; market competition; and changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly report on Form 10-Q for the three months ended September 27, 2013, filed with the Securities and Exchange Commission (SEC) on October 30, 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.

Source: Exelixis, Inc.

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