Exelixis Announces EMA Acceptance of Marketing Authorization Application For COMETRIQ™ (cabozantinib)

November 29, 2012

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 29, 2012-- Exelixis, Inc. (NASDAQ: EXEL) today announced the European Medicines Agency (EMA) has accepted for review the Marketing Authorization Application (MAA) for COMETRIQ™ (cabozantinib) for the proposed indication of treatment of progressive, unresectable, locally advanced, or metastatic medullary thyroid cancer (MTC). The completion of the MAA validation process confirms that the submission is sufficient to permit a substantive review for marketing authorization in the European Union.

The MAA contains data from EXAM, the phase 3 pivotal study of COMETRIQ in progressive, metastatic MTC. This trial also served as the basis for Exelixis' New Drug Application with the U.S. Food and Drug Administration (FDA). The FDA approved COMETRIQ for the treatment of progressive, metastatic MTC on November 29, 2012.

COMETRIQ (cabozantinib) received orphan drug designation in the European Union from the Committee for Orphan Medicinal Products (COMP) for the treatment of MTC.

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 its lead product, COMETRIQ. 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 review for marketing authorization for COMETRIQ in the European Union. Words such as “sufficient,” “permit,” “review,” 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 process. These and other risk factors are discussed under “Risk Factors” and elsewhere in Exelixis’ quarterly report on Form 10-Q for the quarter ended September 28, 2012, filed with the Securities and Exchange Commission (SEC) on November 7, 2012, 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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