



## **Exelixis Announces COMETRIQ™ (cabozantinib) Is Now Available in the U.S.**

January 24, 2013

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 24, 2013-- Exelixis, Inc. (NASDAQ: EXEL) today announced the commercial availability of COMETRIQ® (cabozantinib) for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC). The U.S. Food and Drug Administration (FDA) approved COMETRIQ on November 29, 2012. COMETRIQ is being distributed exclusively through Diplomat Specialty Pharmacy in the U.S.

To help ensure patients have access to COMETRIQ, Exelixis has implemented a comprehensive reimbursement and support program – Exelixis Access Services. The program offers several key components, including co-pay assistance for qualified, commercially-insured patients; medication at no cost for uninsured patients that meet certain financial criteria; and, contributions to independent co-pay assistance charities to help patients who do not qualify for the co-pay assistance program. Exelixis Access Services also offers comprehensive reimbursement support services, such as prior authorization support, benefits investigation and, if needed, appeals support. Information about Exelixis Access Services is available at [www.COMETRIQ.com](http://www.COMETRIQ.com) or 1-855-253-3273.

### **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](http://www.exelixis.com) or [www.COMETRIQ.com](http://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](http://www.exelixis.com) or [www.COMETRIQ.com](http://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](http://www.exelixis.com).

Source: Exelixis, Inc.

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