Exelixis Completes Submission of New Drug Application for Cabozantinib for the Treatment of Medullary Thyroid Cancer

May 30, 2012

-- Priority Review designation requested --

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May. 30, 2012-- Exelixis, Inc. (NASDAQ: EXEL) today announced that it has completed the filing of its rolling New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for cabozantinib as a treatment for patients with progressive, unresectable, locally advanced, or metastatic medullary thyroid cancer (MTC).

The NDA was submitted under the FDA's Fast Track designation, which is designed to potentially accelerate the review of an investigational therapy for an unmet medical need. As part of the NDA filing, Exelixis has requested Priority Review designation from the FDA. If granted, the FDA's goal for completing the review would be six months from the date of receipt of the final submission.

The NDA filing is based on data from the EXAM trial, a phase 3 pivotal trial in patients with advanced MTC. The trial was conducted under a Special Protocol Assessment with the FDA, with progression-free survival (PFS) as the primary endpoint. In October 2011, Exelixis announced top-line results from EXAM demonstrating that the trial had met its primary endpoint of improving PFS: compared with placebo, cabozantinib improved median PFS by 7.2 months. The median PFS on the cabozantinib arm was 11.2 months versus 4.0 months on the placebo arm, with a hazard ratio (HR) of 0.28, (95% CI 0.19, 0.40), $p < 0.0001$.

About Cabozantinib

Cabozantinib is a potent targeted therapy that inhibits MET, VEGFR2 and RET. Cabozantinib is an investigational agent that provides coordinated inhibition of metastasis and angiogenesis to kill tumor cells while blocking their escape pathways. The therapeutic role of cabozantinib is currently being investigated across several tumor types. MET is upregulated in many tumor types, thus facilitating tumor cell escape by promoting the formation of more aggressive phenotypes, resulting in metastasis. MET-driven metastasis may be further stimulated by hypoxic conditions in the tumor environment, which are often exacerbated by selective VEGF-pathway inhibitors. In preclinical studies, cabozantinib has shown powerful tumoricidal, antimetastatic and antiangiogenic effects, including:

- Extensive apoptosis of malignant cells
- Decreased tumor invasiveness and metastasis
- Decreased tumor and endothelial cell proliferation
- Blockade of metastatic bone lesion progression
- Disruption of tumor vasculature

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 cabozantinib (XL184), its most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. Exelixis believes cabozantinib has the potential to be a high-quality, broadly active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. 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 continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib; and the goal for completion of the FDA's review of the referenced NDA. Words such as “goal,” “potential,” “believes,” 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: risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the availability of data at the referenced times; the sufficiency of Exelixis' capital and other resources; the uncertain timing and level of expenses associated with the development of cabozantinib; the uncertainty of the FDA approval process; timely receipt of potential reimbursements, milestones, royalties and profits under Exelixis’ collaborative agreements; Exelixis’ ability to enter into new collaborations; 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 quarter ended March 30, 2012 and Exelixis' other filings with the Securities and Exchange Commission. 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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