Exelixis Provides Update on Ongoing COMET-1 Phase 3 Pivotal Trial in Men with Metastatic Castration-Resistant Prostate Cancer

March 25, 2014

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 25, 2014-- Exelixis, Inc. (NASDAQ:EXEL) announced that the Independent Data Monitoring Committee (IDMC) notified the company today that a planned interim analysis of the COMET-1 phase 3 pivotal trial has been completed, and that the IDMC recommended the trial proceed to its final analysis. Exelixis continues to anticipate top-line data from COMET-1 in 2014.

About the COMET-1 Trial

COMET-1 is a randomized, double-blind, controlled trial designed to enroll 960 patients with mCRPC who have progressed after treatment with docetaxel, abiraterone and/or enzalutamide. All patients in the trial have bone metastases and there is no limit to the number or type of prior treatments. Patients were randomized 2:1 to receive cabozantinib (60 mg daily) or prednisone (5 mg twice daily). The trial is event-driven and has 90% power to detect a 25% reduction in the risk of death (HR = 0.75) at the time of final analysis, which requires 578 events. The current interim analysis after 387 events was also planned to assess if the trial achieved its primary endpoint; it did not include a futility analysis. The secondary endpoint of the trial is bone scan response as assessed by an independent radiology facility (IRF).

About Cabozantinib

Cabozantinib inhibits the activity of tyrosine kinases including MET, VEGFRs and RET. 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.

The European Commission granted COMETRIQ conditional approval for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma (MTC). 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.

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 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 clinical, therapeutic and commercial potential of cabozantinib; and the expected timing for top-line data from the COMET-1 pivotal trial. Words such as “planned,” “continues,” “anticipate,” “believes,” “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 availability of data at the expected times; 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; risks and uncertainties related to Exelixis' compliance with applicable regulatory requirements, including healthcare fraud and abuse laws and post-marketing requirements; Exelixis' dependence on third-party vendors; the sufficiency of Exelixis' capital and other resources; market competition; 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 filed with the Securities and Exchange Commission (SEC) on February 20, 2014 and in 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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Source: Exelixis, Inc.

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