Exelixis Announces Full Patient Enrollment Target Has Been Achieved for COMET-1

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-Phase 3 Pivotal Trial of Cabozantinib in Metastatic Castration-Resistant Prostate Cancer-

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 26, 2013-- Exelixis, Inc. (NASDAQ:EXEL) today announced that the enrollment target of 960 patients has been reached for COMET-1, the company's phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer (mCRPC). The primary endpoint of COMET-1 is overall survival, and Exelixis continues to expect top-line data from COMET-1 and a second pivotal trial in mCRPC, COMET-2, in 2014.

COMET-1 is a randomized, double-blind, placebo-controlled trial designed to enroll 960 patients with mCRPC who have previously been treated with docetaxel, abiraterone acetate 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 are 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. A single interim analysis after 387 events is also planned and will assess if the trial achieved its primary endpoint; it will not include a futility analysis. The secondary endpoint of the trial is bone scan response as assessed by an independent radiology facility (IRF).

"Reaching the COMET-1 enrollment target is a significant milestone for the cabozantinib clinical development program," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "2014 will be an important year for Exelixis as we anticipate top-line data from four pivotal trials of compounds discovered and developed by the company: along with expected data from both COMET trials, we anticipate overall survival data from EXAM, the phase 3 pivotal trial of cabozantinib that served as the basis for its approval to treat progressive, metastatic medullary thyroid cancer. In addition, our partner Genentech, a member of the Roche Group, has guided that it expects data from the pivotal trial of cobimetinib (GDC-0973/XL518), an Exelixis-discovered compound, in combination with vemurafenib as a potential treatment for B-RAF V600 mutation positive, locally advanced or metastatic melanoma."

COMET-1 is one of two ongoing company-sponsored pivotal trials of cabozantinib in mCRPC. The second trial, COMET-2, is a randomized, double-blind, placebo-controlled phase 3 trial evaluating cabozantinib's ability to reduce pain associated with bone metastases. COMET-2 continues to enroll patients, and more information on the trial can be found at www.cometclinicaltrials.com or www.clinicaltrials.gov/ct2/show/NCT01522443. Recently initiated phase 3 pivotal trials of cabozantinib in metastatic renal cell carcinoma and advanced hepatocellular carcinoma are also actively recruiting patients.

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.

About Cobimetinib

Cobimetinib (GDC-0973/XL518) is a potent, highly selective inhibitor of MEK, a serine/threonine kinase that is a component of the RAS/RAF /MEK/ERK pathway. This pathway mediates signaling downstream of growth factor receptors, and is prominently activated in a wide variety of human tumors. In preclinical studies, oral dosing of cobimetinib results in potent and sustained inhibition of MEK in RAS or B-RAF mutant tumor models, and results in significant tumor regression at well-tolerated doses. Cobimetinib was designed to have low penetration into the brain with the aim of minimizing the potential for the CNS side effects reported with previous MEK inhibitors.

Cobimetinib is being developed by Genentech/Roche under a collaboration agreement with Exelixis. As part of the agreement, Exelixis has the option to co-promote in the United States and will be entitled to receive a share in the profits in the United States. Exelixis will receive royalties on any sales of the product that may be commercialized outside the United States.

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 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.

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.COMETRIQ.com.

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 importance of, and designs, plans and goals for, the COMET-1 and COMET-2 trials, and the timing (including for the readout of top-line data) and potential success thereof; the belief that reaching the COMET-1 enrollment target is a significant milestone for the cabozantinib clinical development program; the belief that 2014 will be an important year for Exelixis; anticipated top-line data from four pivotal trials of compounds discovered and developed by Exelixis; recruitment of patients in the recently initiated phase 3 pivotal trials of cabozantinib in metastatic renal cell carcinoma and advanced hepatocellular carcinoma; and the continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib and cobimetinib (GDC-0973/XL518). Words such as “continues,” “expect,” “designed,” “planned,” “will,” “endpoint,” “significant,” “milestone,” “important,” “anticipate,” “potential,” “actively,” “recruiting,” “believe,” 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 or cobimetinib (GDC-0973/XL518) 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; Exelixis' dependence on its relationship with Genentech/Roche for the development of cobimetinib (GDC-0973/XL518) and Exelixis’ ability to maintain its rights under the collaboration; the uncertainty of regulatory approval processes; the sufficiency of Exelixis' capital and other resources; 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 June 28, 2013, filed with the Securities and Exchange Commission (SEC) on August 6, 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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