Exelixis Completes Enrollment of the METEOR Phase 3 Pivotal Trial of Cabozantinib in Metastatic Renal Cell Carcinoma

November 6, 2014

-- Top-Line Data from METEOR Expected in Q2 2015 --

-- Primary Analysis of PFS Endpoint to Be Conducted on First 375 Patients Enrolled --

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 6, 2014-- Exelixis, Inc. (NASDAQ:EXEL) today announced that the enrollment target of 650 patients has been reached for METEOR, the company's phase 3 pivotal trial of cabozantinib in patients with metastatic renal cell carcinoma (RCC) who have experienced disease progression following treatment with at least one VEGFR tyrosine kinase inhibitor (TKI). Top-line efficacy and safety data from METEOR are now expected in the second quarter of 2015.

"METEOR was designed to evaluate cabozantinib's potential as a treatment for metastatic renal cell carcinoma, an aggressive form of the disease that is usually incurable," said Toni Choueiri, MD, clinical director of the Lank Center for Genitourinary Oncology and director of the kidney cancer center, Dana-Farber Cancer Institute. "Recent drug development efforts in RCC have focused on single targets, but there is a compelling body of evidence suggesting a potential advantage in targeting the VEGFR and MET signaling pathways simultaneously. Since cabozantinib inhibits both of these pathways, this trial provides an exciting test of this hypothesis."

Michael M. Morrissey, Ph.D., President and CEO of Exelixis, commented: "With enrollment in METEOR completed, Exelixis has achieved one of its major objectives for the second half of the year. We are grateful for the oncology community's interest and support, as reflected in the trial's rapid enrollment, and we look forward to delivering top-line results from METEOR in the second quarter of 2015."

About METEOR

METEOR is an open-label, event-driven trial with the primary endpoint of progression-free survival (PFS). The trial is being conducted at up to 200 sites in up to 26 countries, and enrollment has been weighted toward Western Europe, North America, and Australia. Patients are randomized 1:1 to receive 60 mg of cabozantinib daily or 10 mg of everolimus daily and have been stratified based on the number of prior VEGFR TKI therapies received, and on commonly applied RCC risk criteria developed by Motzer et al. No cross-over is allowed between the study arms.

Based on available clinical trial data, the primary endpoint of METEOR assumes a median PFS of 5 months for the everolimus arm and 7.5 months for the cabozantinib arm. The trial protocol specifies that the primary analysis will be conducted on the first 375 patients enrolled, and will be triggered after at least 259 events occur, providing 90% power to detect a hazard ratio (HR) of 0.67. Enrollment of the first 375 patients was completed in June 2014.

Secondary endpoints for METEOR include overall survival and objective response rate. The secondary endpoint assumes a median OS of 15 months for the everolimus arm and 20 months for the cabozantinib arm. The study was designed to observe 408 deaths in the entire intention-to-treat population, providing 80% power to detect a HR of 0.75.

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 (MTC).

The European Commission granted COMETRIQ conditional approval for the treatment of adult patients with progressive, unresectable locally advanced or metastatic 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, Inc. is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its development and commercialization efforts primarily on COMETRIQ® (cabozantinib), its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a highly selective inhibitor of MEK, is being evaluated by Roche and Genentech (a member of the Roche Group) in a broad development program under a collaboration with Exelixis. 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: expected timing of future data results with respect to Exelixis' ongoing phase 3 pivotal trial of cabozantinib in patients with metastatic RCC and the continued development and clinical, therapeutic and commercial potential of cabozantinib. Words such as "expected," "potential," "look forward," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in the 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 clinical, therapeutic and commercial value of cabozantinib; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; the general sufficiency of Exelixis' capital and other resources and the specific risk of unforeseen expenses that could diminish Exelixis' financial ability to support its operations through the release of top-line results from METEOR; the uncertain timing and level of expenses associated with the development of cabozantinib; risks related to Exelixis' ability to implement its previously-announced workforce reduction according to plan and its impact on Exelixis' business; charges, expenses and cash expenditures resulting from the referenced workforce reduction; market competition; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Exelixis' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 4, 2014 and in Exelixis' other filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. 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.

Exelixis, Inc.
Susan Hubbard, 650-837-8194
Investor Relations and Corporate Communications
shubbard@exelixis.com