Data From METEOR Pivotal Trial of Cabozantinib in Advanced Renal Cell Carcinoma Accepted as Late-Breaker Presentation in Presidential Session at European Cancer Congress 2015

August 24, 2015

-- Two Presentations of Cobimetinib in Advanced Melanoma Also Accepted --

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 24, 2015-- Exelixis, Inc. (NASDAQ:EXEL) today announced that data from clinical trials of cabozantinib and cobimetinib will be the subject of three presentations at the European Cancer Congress (ECC) 2015, which will be held September 25-29, 2015, in Vienna, Austria.

METEOR Data Accepted for Oral Presentation in Presidential Session

Detailed data from METEOR, the phase 3 pivotal trial of cabozantinib in advanced renal cell carcinoma, will be presented at the ECC as a late-breaking abstract in the Presidential Session I on Saturday, September 26, 2015. In July 2015, Exelixis announced that the trial met its primary endpoint, demonstrating a statistically significant increase in progression-free survival for cabozantinib versus an active comparator, everolimus, in a population of patients who experienced disease progression following treatment with a VEGF receptor tyrosine kinase inhibitor.

The details of the presentation are as follows:

- ***Abstract 4LBA: Late-Breaking Abstract: Cabozantinib versus Everolimus in Patients with Advanced Renal Cell Carcinoma: Results of the Randomized Phase 3 METEOR Trial***

  Toni K. Choueiri, M.D.
  Presidential Session I
  Saturday, September 26, 2015
  Session from 14:30-16:40 CEST (8:30-10:40 a.m. EDT); presentation expected to begin at 16:20 CEST (10:20 a.m. EDT)

Cobimetinib Data Accepted for Proffered Paper and Poster Sessions

Also at the meeting, Exelixis' collaborator Genentech, a member of the Roche Group, will present data on cobimetinib, an Exelixis-discovered compound, in combination with vemurafenib in previously untreated patients with advanced malignant melanoma harboring the BRAF V600 mutation.

The details of the cobimetinib presentations are as follows:

- ***Abstract 25LBA: Late-Breaking Abstract: Impact of Baseline Genetic Heterogeneities on Progression-Free Survival (PFS) in Patients (pts) with Advanced BRAFV600-mutated Melanoma Treated with Cobimetinib (COBI) + Vemurafenib (VEM) in the phase 3 coBRIM Study***

  Professor Grant McArthur
  Proffered Paper Session: Melanoma and Skin Cancer I
  Sunday, September 27, 2015
  Session from 11:30-12:30 CEST (5:30-6:30 a.m. EDT); presentation expected to begin at 12:10 CEST (6:10 a.m. EDT)
  Hall A2

- ***Abstract 3340: Treatment beyond Progression in Advanced BRAF-mutated Melanoma with Vemurafenib and Cobimetinib: Results from the BRIM7 Trial***

  Karl Lewis, M.D.
  Poster Session: Melanoma and Skin Cancer
  Sunday, September 27, 2015
  Session from 16:45-18:45 CEST (10:45 a.m. - 12:45 p.m. EDT)
  Hall C, Poster 217

About Cabozantinib

Cabozantinib inhibits the activity of tyrosine kinases including MET, VEGF receptors, AXL, 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 the Cobimetinib Development Collaboration

Exelixis discovered cobimetinib internally and advanced the compound to investigational new drug (IND) status. In late 2006, Exelixis entered into a collaboration agreement with Genentech, under which Exelixis received initial upfront and milestone payments in connection with signing the agreement and submitting the IND. Exelixis was responsible for development of cobimetinib through the determination of the maximum tolerated dose in phase 1, at which point Genentech exercised its option to further develop the compound.

In November 2013, Exelixis exercised its option to co-promote cobimetinib, if approved, in the United States. Exelixis is entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and will share in the U.S. marketing and commercialization costs. Exelixis is eligible to receive royalties on any sales of the product outside the United States.

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 cabozantinib, its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a 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.

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