# Cabozantinib and Cobimetinib to Be Featured in Ten Presentations at 2014 ASCO Annual Meeting

May 14, 2014

***- Nine presentations of cabozantinib data in prostate, urothelial, and other cancers -***

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 14, 2014-- Exelixis, Inc. (NASDAQ: EXEL) today announced that cabozantinib and cobimetinib will be the subject of ten presentations at the upcoming 2014 Annual Meeting of the American Society of Clinical Oncology (ASCO). The meeting, which will be held May 30 to June 3, 2014 in Chicago, Illinois, is expected to draw more than 25,000 oncology professionals from around the world.

**The full roster of cabozantinib presentations expected at the meeting (all times Central Daylight Time):**

Oral Presentation

- Abstract 4501: *"Effect of cabozantinib on immunosuppressive subsets in metastatic urothelial carcinoma."*
  [Note: This is an NCI-CTEP study.]

  Dr. Andrea Apolo, Center for Cancer Research, National Cancer Institute, Bethesda, MD
  Oral Abstract Session: Genitourinary Cancer
  Monday, June 2, 9:45 a.m. - 12:45 p.m., E Hall D1 (talk from 9:57-10:09 a.m.)

Poster Discussion Presentation

- Abstract 5027/Poster 42: "*Phase 1 dose finding study of cabozantinib (cabo) + abiraterone (abi) combination therapy in castration resistant prostate cancer (CRPC): An investigator-sponsored study."*
  [Note: This is an Investigator-Sponsored Trial.]

  Dr. Christopher Sweeney, The Dana Farber Cancer Institute, Boston, MA
  Poster Highlights Session: Genitourinary (Prostate) Cancer
  Saturday, May 31, 1:15-4:15 p.m. (poster display, E354b); 4:45-6:00 p.m. (discussion, E354b)

- Abstract 8014/Poster 28: *"Phase II trial of XL184 (cabozantinib) plus erlotinib in patients (pts) with advanced EGFR-mutant non-small cell lung cancer (NSCLC) with progressive disease (PD) on epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy: a California Cancer Consortium phase II trial (NCI 9303)."*
  [Note: This is an NCI-CTEP study.]

  Dr. Karen Reckamp, City of Hope Cancer Center, Duarte, California
  Poster Highlights Session: Lung Cancer
  Tuesday, June 3, 8:00–11:00 a.m. (poster display, room E354b); 11:30 a.m.–12:45 p.m. (discussion, E354b)

General Poster Presentations

- Abstract TPS4150/Poster 234A: *"Phase 3 randomized, double-blind, controlled study of cabozantinib (XL184) versus placebo in subjects with hepatocellular carcinoma who have received prior sorafenib (CELESTIAL; NCT01908426)."*

  Dr. Ghassan K. Abou-Alfa, Memorial Sloan-Kettering Cancer Center, New York
  General Poster Session: Gastrointestinal (Noncolorectal) Cancer
  Saturday, May 31, 8:00-11:45 a.m., South Hall A2
  [Note: This is a Trials in Progress abstract.]

- Abstract TPS4157/Poster 237B: *"A phase II trial of cabozantinib in patients with carcinoid and pancreatic neuroendocrine tumors."*
  [Note: This is an Investigator-Sponsored Trial, and a Trials in Progress abstract.]

  Dr. Jason Faris, Massachusetts General Hospital, Boston, MA
  General Poster Session: Gastrointestinal (Noncolorectal) Cancer
  Saturday, May 31, 8:00-11:45 a.m., South Hall A2

- Abstract TPS5629/Poster 402A: *"Phase II study of XL184 (Cabozantinib) in recurrent or metastatic endometrial cancer: A trial of the PMH, Chicago and California Phase II Consortia."*
  [Note: This is an NCI-CTEP study, and a Trials in Progress abstract.]

  Dr. Michelle Wilson, Princess Margaret Cancer Centre, Toronto, Ontario, Canada
  General Poster Session: Gynecologic Cancer
  Saturday, May 31, 8:00-11:45 a.m., South Hall A2

- Abstract 10078/Poster 379: *"A phase I study of Cabozantinib (XL184) in children and adolescents with recurrent or refractory solid tumors, including CNS tumors: A Children's Oncology Group phase I consortium trial."*
  [Note: This is an NCI-CTEP study.]

  Dr. Meredith K. Chuk, The Johns Hopkins Hospital, Baltimore, MD
  General Poster Session: Pediatric Oncology
  Monday, June 2, 8:00-11:45 a.m., South Hall A2

- Abstract TPS4601/Poster 163A: *"Phase 3 randomized study of cabozantinib (XL184) versus everolimus in subjects with clear cell renal cell carcinoma (METEOR)."*
  [Note: This is a Trials in Progress abstract.]

  Dr. Toni K. Choueiri, Dana Farber Cancer Institute, Boston, MA
  General Poster Session: Genitourinary Cancer
  Monday, June 2, 1:15-5:00 p.m**.**, South Hall A2

- Abstract 5072/Poster 201: *"A safety study of cabozantinib (C) plus docetaxel (D) and prednisone (P) in metastatic castrate-resistant prostate cancer (mCRPC)."*
  [Note: This is an NCI-CTEP study.]

  Dr. Fatima Karzai, Center for Cancer Research, National Cancer Institute, Bethesda, MD
  General Poster Session: Genitourinary Cancer
  Monday, June 2, 1:15–5:00 p.m., South Hall A2

**The cobimetinib oral presentation expected at the meeting (time Central Daylight Time):**

- Abstract 9006: ***"****Metabolic tumor burden for prediction of overall survival following combined BRAF/MEK inhibition in patients with advanced BRAF mutant melanoma."*

  Prof. Grant A. MacArthur, Peter MacCallum Cancer Centre, Victoria, Australia
  Oral Abstract Session: Melanoma/Skin Cancers
  Monday, June 2, 3:00-6:00 p.m, E Arie Crown Theater (talk from 4:36–4:48 p.m.)

**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 Cobimetinib**

Cobimetinib (formerly GDC-0973/XL518) is an 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 resulted in sustained inhibition of MEK in RAS or BRAF mutant tumor models. Cobimetinib is being developed by Roche and Genentech, a member of the Roche Group, under a collaboration with Exelixis.

**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, Inc. (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.



Source: Exelixis, Inc.

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