Cabozantinib and Cobimetinib to Be Featured in Fourteen Presentations at 2015 ASCO Annual Meeting

April 30, 2015

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 30, 2015-- Exelixis, Inc. (NASDAQ: EXEL) today announced that the Exelixis-discovered compounds cabozantinib and cobimetinib will be the subjects of fourteen presentations at the upcoming 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO). The meeting, which will be held from May 29 to June 2, 2015 in Chicago, Illinois, is expected to draw 30,000 oncology professionals from around the world.

Cabozantinib will be the subject of eight presentations primarily from studies conducted under the company's Investigator-Sponsored Trial program and collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP), as well as from one Exelixis-sponsored trial. The full roster of cabozantinib presentations expected at the meeting (all times Central Daylight Time):

Oral Presentations

- **Abstract 8003:** ***"Cabozantinib (C), erlotinib (E) or the combination (E+C) as 2nd or 3rd line therapy in patients with EGFR wild-type (wt) NSCLC: a randomized phase 2 trial of the ECOG-ACRIN Cancer Research Group (E1512)."***
  Dr. Joel Neal, Stanford University Medical Center, Palo Alto, CA
  Oral Abstract Session: Lung Cancer – Non-Small Cell Metastatic
  Sunday, May 31, 8:00–11:00 a.m., N Hall B1 (talk from 8:36-8:48 a.m.)
  [Note: This is an NCI-CTEP study.]

- **Abstract 8007:** ***"Phase II study of cabozantinib for patients with advanced RET-rearranged lung cancers."***
  Dr. Alexander Drilon, Memorial Sloan Kettering Cancer Center, New York, NY
  Oral Abstract Session: Lung Cancer – Non-Small Cell Metastatic
  Sunday, May 31, 8:00–11:00 a.m., N Hall B1 (talk from 10:12–10:24 a.m.)
  [Note: This is an Investigator-Sponsored Trial.]

Poster Discussions

- **Abstract 6012:** ***"Final overall survival analysis of EXAM, an international, double-blind, randomized, placebo-controlled phase III trial of cabozantinib (Cabo) in medullary thyroid carcinoma (MTC) patients with documented RECIST progression at baseline."***
  Dr. Martin Schlumberger, Institut Gustave Roussy, Paris, France
  Poster Session: Head and Neck Cancer
  Poster presented Saturday, May 30, 1:15–4:45 p.m., S Hall A (Poster 335); discussed later in the day, from 4:45-6:00 p.m., in Room S 406.

- **Abstract 8021:** ***"Response to crizotinib and cabozantinib in stage IV lung adenocarcinoma patients with mutations that cause MET exon 14 skipping."***
  Dr. Paul Paik, Memorial Sloan Kettering Cancer Center, New York, NY
  Poster Session: Lung Cancer
  Monday, June 1, 8:00–11:30 a.m., S Hall A (Poster 343); discussed later in the day, from 3:00-4:15 p.m., in E Hall D2
  [Note: This is an Investigator-Sponsored Trial.]

General Poster Presentations

- **Abstract 1080:** ***"A Phase II study of cabozantinib for metastatic triple-negative breast cancer (TNBC)."***
  Dr. Sara Tolaney, The Dana Farber Cancer Institute, Boston, MA
  Poster Session: Breast Cancer – Triple-Negative/Cytotoxics/Local Therapy
  Saturday, May 30, 8:00 a.m. – 11:30 a.m., S Hall A (Poster 194)
  [Note: This is an Investigator-Sponsored Trial.]

- **Abstract 5037:** ***"Phase 1 study with expansion cohorts of cabozantinib (C) + abiraterone (A) in metastatic***

castration resistant prostate cancer."
Dr. Christopher Sweeney, The Dana Farber Cancer Institute, Boston, MA
Poster Session: Genitourinary (Prostate) Cancer
Saturday, May 30, 1:15–4:45 p.m., S Hall A (Poster 29)
[Note: This is an Investigator-Sponsored Trial.]

- **Abstract 8087:** ***"Biomarker analysis of a phase II trial of cabozantinib and erlotinib in patients (pts) with EGFR-mutant NSCLC with epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) resistance: A California Cancer Consortium Phase II Trial (NCI 9303)."***
  Dr. Karen Reckamp, City of Hope Cancer Treatment Center, Duarte, CA
  Poster Session: Lung Cancer – Non-Small Cell Metastatic
  Monday, June 1, 8:00–11:30 a.m., S Hall A (Poster 411)
  [Note: This is an NCI-CTEP study.]

- **Abstract #TPS9087:** ***"Randomized phase II study comparing the MET inhibitor cabozantinib to temozolomide (TMZ) or dacarbazine (DTIC) in ocular melanoma: A091201."***
  Dr. Jason John Luke, University of Chicago
  Poster Session: Melanoma/Skin Cancers
  Monday, June 1, 1:15–4:45 p.m., S Hall A (Poster 326a)
  [Note: This is an NCI-CTEP study and a Trials in Progress abstract.]

Cobimetinib will be the subject of six presentations from Genentech-sponsored trials of the compound. The full roster of cobimetinib presentations expected at the meeting (all times Central Daylight Time):

Oral Presentations

- **Abstract 9006:** ***"Update of progression-free survival (PFS) and correlative biomarker analysis from coBRIM: Phase III study of cobimetinib (cobi) plus vemurafenib (vem) in advanced BRAF-mutated melanoma."***
  Dr. James M. G. Larkin, The Royal Marsden NHS Foundation Trust
  Oral Abstract Session: Melanoma/Skin Cancers
  Saturday, May 30, 1:15–4:15 p.m., Room E354b (talk from 3:15–3:27 p.m.)

Poster Presentations

- **Abstract 2573:** ***"Population pharmacokinetics and dosing implications for cobimetinib in patients with solid tumors."***
  Kelong Han, Genentech Inc., South San Francisco, CA
  Poster Session: Developmental Therapeutics – Clinical Pharmacology and Experimental Therapeutics
  Saturday, May 30, 8:00–11:30 a.m., S Hall A (Poster 289)

- **Abstract 9020:** ***"Extended follow-up results of phase 1B study (BRIM7) of vemurafenib (VEM) with cobimetinib (COBI) in BRAF-mutant melanoma."***
  Dr. Anna Pavlick, New York University Medical Center, New York, NY
  Poster Session: Melanoma/Skin Cancers
  Monday, June 1, 1:15–4:45 p.m., S Hall A (Poster 263)

- **Abstract 9021:** ***"Quality-of-life (QOL) assessment in patients (pts) with metastatic melanoma receiving vemurafenib (V) and cobimetinib (C)."***
  Dr. Brigitte Dréno, Nantes University, Nantes, France
  Poster Session: Melanoma/Skin Cancers
  Monday, June 1, 1:15 – 4:45 p.m., S Hall A (Poster 264)

- **Abstract 9033:** ***"Clinical features of cobimetinib (COBI)–associated serous retinopathy (SR) in BRAF-mutated melanoma patients (pts) treated in the coBRIM study."***
  Dr. Luis de la Cruz-Merino, Hospital Universitario Virgen Macarena, Seville, Spain
  Poster Session: Melanoma/Skin Cancers
  Monday, June 1, 1:15 p.m. – 4:45 p.m., S Hall A (Poster 276)

- **Abstract TPS9088:** ***"Phase 2 study of cobimetinib in combination with vemurafenib in active melanoma brain metastases (coBRIM-B)."***
  Dr. Melissa K. Yee, University of Pittsburgh Cancer Institute, Pittsburgh, PA
  Poster Session: Melanoma/Skin Cancers
  Monday, June 1, 1:15 p.m. – 4:45 p.m., S Hall A (Poster 326b)

[Note: This is a Trials in Progress abstract.]

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 the Cobimetinib and Vemurafenib Combination

Cobimetinib is a selective inhibitor that blocks the activity of MEK, a protein kinase that is part of a key pathway (the RAS-RAF-MEK-ERK pathway) that promotes cell division and survival. This pathway is frequently activated in human cancers including melanoma, where mutation of one of its components (BRAF) causes abnormal activation in about 50% of cases. Tumors with BRAF mutations may develop resistance and subsequently progress after treatment with a BRAF inhibitor. About 50% of patients with BRAF mutation positive melanoma experience a tumor response when treated with a BRAF inhibitor, however development of resistance and subsequent tumor progression limits treatment benefit. Clinical and preclinical analyses indicated that reactivation of the MEK-ERK pathway may underlie development of resistance to BRAF inhibitors in many progressing tumors, and that co-treatment with a BRAF and MEK inhibitor delays the emergence of resistance in the preclinical setting, providing the rationale for testing the combination of vemurafenib and cobimetinib in clinical trials. In addition to the combination with vemurafenib in melanoma, cobimetinib is also being investigated in combination with several investigational medicines, including an immunotherapy, in several tumor types, including non-small cell lung cancer, colorectal cancer, triple-negative breast cancer and melanoma.

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 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.

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