Exelixis-discovered Compounds To Be Featured in 15 Presentations at the ESMO 2016 Congress

August 31, 2016

- CABOSUN results accepted as late-breaker presentation in oral session on October 8 -

SOUTH SAN FRANCISCO--(BUSINESS WIRE)--Aug. 31, 2016-- Exelixis, Inc. (NASDAQ:EXEL) today announced that data from clinical trials of cabozantinib and cobimetinib will be the subject of 15 presentations at the European Society for Medical Oncology (ESMO) 2016 Congress in Copenhagen, October 7 – 11, 2016.

Detailed results from CABOSUN, a randomized phase 2 clinical trial of cabozantinib compared with sunitinib in patients with previously untreated advanced renal cell carcinoma (RCC), will be presented at ESMO as a late-breaking abstract in the Genitourinary Tumours, Non-Prostate oral presentation session on Saturday, October 8. Additional poster presentations will detail the investigation of cabozantinib in other cancer settings, including in combination with nivolumab in metastatic urothelial carcinoma and other genitourinary cancers, as well as the evaluation of cobimetinib in combination studies across multiple tumor types.

"This year's ESMO Congress provides Exelixis and our partners with the opportunity to present data across a broad spectrum of cancers and potential treatment combinations," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "We look forward to the first presentation of the CABOSUN data, which will provide more detail about the statistically significant and clinically meaningful improvement in progression-free survival for cabozantinib in patients with advanced renal cell carcinoma in the front-line setting. Our focus remains on further examining the potential of our therapies and moving these medicines through clinical development so they are available to patients and physicians as quickly as possible."

Cabozantinib to be featured in eight presentations
The full schedule of cabozantinib presentations expected at the meeting is as follows:

Oral Presentation
[LBA30] "CABOzantinib versus SUNitinib (CABOSUN) as initial targeted therapy for patients with metastatic renal cell carcinoma (mRCC) of poor and intermediate risk groups: Results from ALLIANCE A031203 Trial."
Dr. Toni Choueiri, Director, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts, USA
Session: Genitourinary Tumours, Non-Prostate
Oral presentation Saturday, October 8, 9:15 – 9:30 a.m. CEST, Madrid
Note: This is a National Cancer Institute Cancer Therapy Evaluation Program (NCI-CTEP) study.

Poster Discussion
[774PD] "A phase I study of cabozantinib plus nivolumab (CaboNivo) in patients (pts) with refractory metastatic urothelial carcinoma (mUC) and other genitourinary (GU) tumors."
Dr. Andrea Borghese Apolo, Genitourinary Malignancies Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, USA
Session: Genitourinary Tumours, Non-Prostate
Poster presented Sunday, October 9, 4:30 – 5:30 p.m. CEST, Athens
Note: This is an NCI-CTEP study.

Poster Presentations
[787P] "A phase II study of cabozantinib in patients (pts) with relapsed/refractory metastatic urothelial carcinoma (mUC)."
Dr. Rosa Nadal, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, Maryland, USA
Session: Genitourinary Tumours, Non-Prostate
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E
Note: This is an NCI-CTEP study.

[814P] "Efficacy of cabozantinib (cabo) vs everolimus (eve) by metastatic site and tumor burden in patients (pts) with advanced renal cell carcinoma (RCC) in the phase 3 METEOR trial."
Dr. Thomas Powles, Barts Cancer Institute, Cancer Research UK Experimental Cancer Medicine Centre, Queen Mary University of London, Royal Free NHS Trust, London, GB
Session: Genitourinary Tumours, Non-Prostate
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[815P] "Evaluation of the novel "trial within a trial" design of METEOR, a randomized phase 3 trial of cabozantinib versus everolimus in patients (pts) with advanced renal cell carcinoma (RCC)."
Colin Hessel, Exelixis, Inc., South San Francisco, California, USA
Session: Genitourinary Tumours, Non-Prostate
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[816P] "Quality of life (QoL) in the phase 3 METEOR trial of cabozantinib vs everolimus for advanced renal cell carcinoma (RCC)."

Dr. David Cella, Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
Session: Genitourinary Tumours, Non-Prostate
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[818P] "Analysis of regional differences in the phase 3 METEOR study of cabozantinib (cabo) versus everolimus (eve) in advanced renal cell carcinoma (RCC)."
Dr. Nizar Tannir, University of Texas, MD Anderson Cancer Center, Houston, Texas, USA
Session: Genitourinary Tumours, Non-Prostate
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[1421TiP] "A randomized double-blind phase II study evaluating the role of maintenance therapy with cabozantinib in high grade undifferentiated uterine sarcoma (HGUS) after stabilization or response to doxorubicin +/- ifosfamide following surgery or in metastatic first line treatment."
Dr. Isabelle Ray-Coquard, Cancer Research Center of Lyon, Lyon, France
Session: Sarcoma
Poster presented Monday, October 10, 1 – 2 p.m. CEST, Hall E
Note: This is an investigator-sponsored trial.

Cobimetinib to be featured in seven presentations
Also at the meeting, Exelixis' collaborator Genentech, a member of the Roche Group, will present data on cobimetinib, an Exelixis-discovered compound, in disease settings including metastatic colorectal cancer, melanoma and breast cancer. The full schedule of cobimetinib presentations expected at the meeting is as follows:

Oral Presentation
[1111O] "Genomic features of complete responders (CR) versus fast progressors (PD) in patients with BRAFV600-mutated metastatic melanoma treated with cobimetinib + vemurafenib or vemurafenib alone."
Y. Yan, Genentech, Inc., South San Francisco, California, USA
Session: Melanoma and Other Skin Tumours
Oral presentation Saturday, October 8, 3:00 – 3:15 p.m. CEST, Copenhagen

Poster Discussion
[1109PD] "Preliminary safety and clinical activity of atezolizumab combined with cobimetinib and vemurafenib in BRAF V600-mutant metastatic melanoma."
Dr. Patrick Hwu, MD Anderson Cancer Center, Houston, Texas, USA
Session: Melanoma and Other Skin Tumours
Poster presented Monday, October 10, 11 a.m. – 12 p.m. CEST, Rome

Poster Presentations
[470P] "Efficacy and safety of cobimetinib (cobi) and atezolizumab (atezo) in an expanded phase 1B study of microsatellite-stable (MSS) metastatic colorectal cancer (mCRC)."
Dr. Jayesh Desai, Peter MacCallum Cancer Centre, Melbourne, Australia
Session: Genitourinary Tumours, Colorectal
Poster presented Saturday, October 8, 1– 2 p.m. CEST, Hall E

[1142P] "Prognostic subgroups and impact of treatment for post-progression overall survival (ppOS) in patients (pts) with BRAFV600-mutated metastatic melanoma treated with decarbazine (DTIC) or vemurafenib (VEM) +/- cobimetinib (COBI): A pooled analysis."
Dr. Paolo Ascierto, National Tumor Institute "Fondazione G. Pascale," Naples, Italy
Session: Melanoma and Other Skin Tumours
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[1138P] "Cobimetinib plus vemurafenib to treat unresectable or metastatic melanoma: Data from the French temporary authorization for use."
Dr. Nicolas Meyer, Institute Claudius Regaud, Toulouse, France
Session: Melanoma and Other Skin Tumours
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[1156TiP] "CONVERCE: Evaluation of cobimetinib and vemurafenib combination treatment in patients with brain metastases from BRAFV600 mutated melanoma."
Dr. Thierry Lesimple, Centre Eugène Marquis, Rennes, France
Session: Melanoma and Other Skin Tumours
Poster presented Sunday, October 9, 1 – 2 p.m. CEST, Hall E

[286P] "First-line cobimetinib (C) + paclitaxel (P) in patients (pts) with advanced triple-negative breast cancer (TNBC): Updated results and tumoral immune cell infiltration data from the phase 2 COLET study."
Dr. David Miles, Mount Vernon Cancer Centre, Northwood, United Kingdom
Session: Breast Cancer, Locally Advanced and Metastatic
Poster presented Monday, October 10, 1– 2 p.m. CEST, Hall E

About the CABOSUN Study

On May 23, 2016, Exelixis announced that CABOSUN met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in PFS compared with sunitinib in patients with advanced intermediate- or poor-risk RCC. CABOSUN is being conducted by The Alliance for Clinical Trials in Oncology as part of Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP). Exelixis is discussing the results with regulatory authorities and evaluating potential next steps in the development and submission strategy for cabozantinib as a first-line treatment for patients with advanced RCC.

CABOSUN is a randomized, open-label, active-controlled phase 2 trial that enrolled 157 patients with advanced RCC determined to be intermediate- or poor-risk by the International Metastatic RCC Database Consortium (IMDC) criteria. Patients were randomized 1:1 to receive cabozantinib (60 mg once daily) or sunitinib (50 mg once daily, 4 weeks on followed by 2 weeks off). The primary endpoint was progression-free survival. Secondary endpoints included overall survival and objective response rate. Eligible patients were required to have locally advanced or metastatic clear-cell RCC, ECOG performance status 0-2, and had to be intermediate or poor risk, per the IMDC Criteria (Heng JCO 2009). Prior systemic treatment for RCC was not permitted.

Please see Important Safety Information below and full U.S. prescribing information at https://cabometyx.com/downloads/cabometyxuspi.pdf.

About Advanced Renal Cell Carcinoma

The American Cancer Society's 2016 statistics cite kidney cancer as among the top ten most commonly diagnosed forms of cancer among both men and women in the U.S.[1] Clear cell RCC is the most common type of kidney cancer in adults.[2] If detected in its early stages, the five-year survival rate for RCC is high; for patients with advanced or late-stage metastatic RCC, however, the five-year survival rate is only 12 percent, with no identified cure for the disease. [1] Approximately 30,000 patients in the U.S. and 68,000 globally require treatment.[3]

The majority of clear cell RCC tumors have lower than normal levels of a protein called von Hippel-Lindau, which leads to higher levels of MET, AXL and VEGF.[4,5] These proteins promote tumor angiogenesis (blood vessel growth), growth, invasiveness and metastasis.[6-9] MET and AXL may provide escape pathways that drive resistance to VEGFR inhibitors.[5,6]

About CABOMETYX™ (cabozantinib)

CABOMETYX is the tablet formulation of cabozantinib. Its targets include MET, AXL and VEGFR-1, -2 and -3. In preclinical models, cabozantinib has been shown to inhibit the activity of these receptors, which are involved in normal cellular function and pathologic processes such as tumor angiogenesis, invasiveness, metastasis and drug resistance.

CABOMETYX is available in 20 mg, 40 mg or 60 mg doses. The recommended dose is 60 mg orally, once daily.

On April 25, 2016, the FDA approved CABOMETYX tablets for the treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy.

On February 29, 2016, Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib indications outside of the United States, Canada and Japan. On July 22, 2016 Exelixis and its partner Ipsen announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA) provided a positive opinion for CABOMETYX for the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy and recommended it for marketing authorization. The marketing authorization application (MAA) has been granted accelerated assessment, making it eligible for a 150-day review, versus the standard 210 days.

Important Safety Information

Hemorrhage: Severe hemorrhage occurred with CABOMETYX. The incidence of Grade ≥3 hemorrhagic events was 2.1% in CABOMETYX-treated patients and 1.6% in everolimus-treated patients. Fatal hemorrhages also occurred in the cabozantinib clinical program. Do not administer CABOMETYX to patients that have or are at risk for severe hemorrhage.

Gastrointestinal (GI) Perforations and Fistulas: Fistulas were reported in 1.2% (including 0.6% anal fistula) of CABOMETYX-treated patients and 0% of everolimus-treated patients. GI perforations were reported in 0.9% of CABOMETYX-treated patients and 0.6% of everolimus-treated patients. Fatal perforations occurred in the cabozantinib clinical program. Monitor patients for symptoms of fistulas and perforations. Discontinue CABOMETYX in patients who experience a fistula that cannot be appropriately managed or a GI perforation.

Thrombotic Events: CABOMETYX treatment results in an increased incidence of thrombotic events. Venous thromboembolism was reported in 7.3% of CABOMETYX-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Events of arterial thromboembolism were reported in 0.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETYX in patients who develop an acute myocardial infarction or any other arterial thromboembolic complication.

Hypertension and Hypertensive Crisis: CABOMETYX treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥3) of CABOMETYX-treated patients and 7.1% (3.1% Grade ≥3) of everolimus-treated patients. Monitor blood pressure prior to initiation and regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue CABOMETYX if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

Diarrhea: Diarrhea occurred in 74% of patients treated with CABOMETYX and in 28% of patients treated with everolimus. Grade 3 diarrhea occurred in 11% of CABOMETYX-treated patients and in 2% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 diarrhea or Grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to diarrhea occurred in 26% of patients.

Palmar-Plantar Erythrodysesthesia Syndrome (PPES): Palmar-plantar erythrodysesthesia syndrome (PPES) occurred in 42% of patients treated with CABOMETYX and in 6% of patients treated with everolimus. Grade 3 PPES occurred in 8.2% of CABOMETYX-treated patients and in <1% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to PPES occurred in 16% of patients.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Perform an evaluation for RPLS in any patient presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

Embryo-fetal Toxicity: CABOMETYX can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the last dose.

Adverse Reactions: The most commonly reported (≥25%) adverse reactions are: diarrhea, fatigue, nausea, decreased appetite, PPES, hypertension, vomiting, weight decreased, and constipation.

Drug Interactions: Strong CYP3A4 inhibitors and inducers: Reduce the dosage of CABOMETYX if concomitant use with strong CYP3A4 inhibitors cannot be avoided. Increase the dosage of CABOMETYX if concomitant use with strong CYP3A4 inducers cannot be avoided.

Lactation: Advise a lactating woman not to breastfeed during treatment with CABOMETYX and for 4 months after the final dose.

Reproductive Potential: Contraception—Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the final dose. **Infertility —**CABOMETYX may impair fertility in females and males of reproductive potential.

Hepatic Impairment: Reduce the CABOMETYX dose in patients with mild (Child-Pugh score [C-P] A) or moderate (C-P B) hepatic impairment. CABOMETYX is not recommended for use in patients with severe hepatic impairment.

Please see full Prescribing Information at https://cabometyx.com/downloads/cabometyxuspi.pdf.

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. The U.S. Food & Drug Administration approved cobimetinib for the treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib, in 2015. 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. (Nasdaq: EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S.) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

Forward-Looking Statement Disclaimer

This press release contains forward-looking statements, including, without limitation, statements related to: future data presentations from clinical trials of cabozantinib and cobimetinib at ESMO, including detailed results from CABOSUN; the opportunity for Exelixis and its partners to present data across a broad spectrum of cancers and potential treatment combinations provided by ESMO; Exelixis' focus on further examining the potential of its therapies and moving medicines through clinical development so they are available to patients and physicians as quickly as possible; the potential next steps in the development and submission strategy for cabozantinib as a first-line treatment for patients with advanced RCC; the timing for review of the CHMP's positive opinion of the MAA for cabozantinib for the treatment advanced RCC in adults following prior VEGF-targeted therapy; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "will," "opportunity," "look forward," "focus," "potential," "eligible," "committed," 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, projections 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. 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 referenced times; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; the sufficiency of Exelixis' resources; costs associated with Exelixis' research and development, commercialization and other activities; the degree of market acceptance of CABOMETYX and COMETRIQ and the availability of coverage and reimbursement for CABOMETYX and COMETRIQ; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX or COMETRIQ; Exelixis' dependence on its relationship with Ipsen, including, the level of Ipsen's investment in the resources necessary to successfully commercialize cabozantinib in the territories where it is approved; Exelixis' dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; 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 August 3, 2016, and in Exelixis' future 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.

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