Cabozantinib to Be Featured in 13 Presentations at ESMO 2018 Congress

October 8, 2018

– Presentations to include results from the dose escalation stage of phase 1b COSMIC-021 study of cabozantinib in combination with atezolizumab in previously untreated advanced renal cell carcinoma –

ALAMEDA, Calif.--(BUSINESS WIRE)--Oct. 8, 2018-- Exelixis, Inc. (NASDAQ:EXEL) today announced that data from clinical trials of cabozantinib will be the subject of 13 presentations at the European Society for Medical Oncology (ESMO) 2018 Congress, which is being held October 19-23, 2018 in Munich, Germany.

Poster presentations will include results from the dose escalation stage of the phase 1b COSMIC-021 study of cabozantinib in combination with atezolizumab in previously untreated advanced renal cell carcinoma (RCC). Additionally, a poster discussion session will feature a late-breaking abstract evaluating the effect of PD-L1 status on clinical outcomes with cabozantinib in advanced RCC in the CABOSUN and METEOR trials.

"The data at ESMO showcase the potential of cabozantinib across a range of difficult-to-treat cancers," said Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer, Exelixis. "We are especially excited to present results from the dose escalation stage of the COSMIC-021 trial evaluating the combination of cabozantinib and atezolizumab in advanced kidney cancer and look forward to sharing these data and more with the oncology community at this year's ESMO Congress."

Cabozantinib to be featured in 13 presentations
The full schedule of cabozantinib presentations expected at the meeting is as follows:

Proffered Paper Session

[Abstract LBA67] "Cabozantinib in Patients with Advanced Osteosarcomas and Ewing Sarcomas: a French Sarcoma Group (FSG)/ US National Cancer Institute Phase II Collaborative Study"
Antoine Italiano, M.D., Ph.D., Early Phase Trials Unit, Institut Bergonié, Bordeaux, France
Session: Sarcoma
Proffered Paper Session Friday, October 19, 2:00 – 3:30 PM CEST, Hall B3 – Room 21

Poster Discussion

[Abstract LBA34] "PD-L1 Status and Clinical Outcomes to Cabozantinib, Sunitinib and Everolimus in Patients with Metastatic Clear-Cell RCC Treated on CABOSUN and METEOR Clinical Trials"
Toni K. Choueiri, M.D., Dana-Farber Cancer Institute, Boston, Massachusetts, USA
Session: Genitourinary Tumors, Non Prostate
Poster Discussion Session Saturday, October 20, 2:45 – 4:05 PM, CEST, ICM – Room 1

[Abstract 1310PD] "Prospective Genome and Transcriptome Sequencing in Advanced-Stage Neuroendocrine Neoplasms"
Leonidas Apostolidis, M.D., National Center for Tumor Diseases (NCT), Heidelberg, Germany
Session: NETs
Poster Discussion Session Monday, October 22, 11:00 AM – 12:15 PM CEST, Hall B3 – Room 22

Poster Presentations

[Abstract 702P] "Outcomes by Baseline Alpha-Fetoprotein (AFP) Levels in the Phase 3 CELESTIAL Trial of Cabozantinib (C) versus Placebo (P) in Previously Treated Advanced Hepatocellular Carcinoma (HCC)"
R. K. Kelley, M.D., University of California San Francisco Helen Diller Family Comprehensive Cancer Center, San Francisco, California, USA
Session: Poster Display Session
Poster presented Sunday, October 21, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 703P] "Assessment of Disease Burden in the Phase 3 CELESTIAL Trial of Cabozantinib (C) versus Placebo (P) in Advanced Hepatocellular Carcinoma (HCC)"
Jean Frederic Blanc, M.D., Hôpital Haut-Lévêque, CHU Bordeaux, Bordeaux, France
Session: Poster Display Session
Poster presented Sunday, October 21, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 704P] "Outcomes by Prior Transarterial Chemoembolization (TACE) in the Phase 3 CELESTIAL Trial of Cabozantinib (C) versus Placebo (P) in Patients (pts) with Advanced Hepatocellular Carcinoma (HCC)"
Thomas Yau, M.D., Queen Mary Hospital, Hong Kong, China
Session: Poster Display Session
Poster presented Sunday, October 21, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 1829TiP] "A Noninferiority Trial of Cabozantinib (C) Comparing 60 mg vs 140 mg Orally per Day to Evaluate the Efficacy and Safety in Patients (pts) with Progressive, Metastatic Medullary Thyroid Cancer (MTC)"
Jolanta Krajewska, M.D., Ph.D., M. Sklodowska-Curie Institute – Oncology Center, Gliwice, Poland
Session: Poster Display Session

Poster presented Sunday, October 21, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 1913P] "A Guided and Personnalized Treatment in Metastatic Breast Cancer: Optimisation of Gene and Protein Expression in Tumor Tissue"
Emmanuel Seront, M.D., Cliniques Universitaires Saint-Luc King Albert II Institute, Brussels, Belgium
Session: Poster Display Session
Poster presented Sunday, October 21, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 872P] "Phase 1b Study (COSMIC-021) of Cabozantinib in Combination with Atezolizumab: Results of the Dose Escalation Stage in Patients (pts) with Treatment-Naïve Advanced Renal Cell Carcinoma (RCC)"
Neeraj Agarwal, M.D., Huntsman Cancer Center, Salt Lake City, Utah, USA
Session: Poster Display Session
Poster presented Monday, October 22, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 893P] "Cabozantinib in Metastatic Renal Cell Carcinoma (mRCC): Data from UK Expanded Access Program (EAP)"
Alfonso Gomez de Liano Lista, M.D., Barts Cancer Institute, London, England
Session: Poster Display Session
Poster presented Monday, October 22, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 879P] "Activity of Cabozantinib (cabo) after PD-1/PD-L1 Immune Checkpoint Blockade (ICB) in Metastatic Clear Cell Renal Cell Carcinoma (mccRCC)"
Bradley A. McGregor, M.D., Dana-Farber Cancer Institute, Boston, Massachusetts, USA
Session: Poster Display Session
Poster presented Monday, October 22, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 882P] "Potent Natural Killer (NK) and Myeloid Blood Cell Remodeling by Cabozantinib (Cabo) in Pretreated Metastatic Renal Cell Carcinoma (mRCC) Patients (pts)"
Elena Verzoni, M.D., Fondazione IRCCS Istituto Nazionale dei Tumori di Milano, Milan, Italy
Session: Poster Display Session
Poster presented Monday, October 22, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

[Abstract 889P] "Clinical Outcomes of Patients with Metastatic Renal Cell Carcinoma (mRCC) Treated with Vascular Endothelial Growth Factor Receptor (VEGFR) Tyrosine Kinase Inhibitors (TKI) and Mammalian Target of Rapamycin Inhibitors (mTORI) after Immuno-oncology (IO) Checkpoint Inhibitors"
Jeffrey Graham, M.D., Tom Baker Cancer Centre, University of Calgary, Calgary, Alberta, Canada
Session: Poster Display Session
Poster presented Monday, October 22, 12:45 – 1:45 PM CEST, Hall A3 – Poster Area Networking Hub

About CABOMETYX® (cabozantinib)

CABOMETYX tablets are approved in the United States for the treatment of patients with advanced RCC. CABOMETYX tablets are also approved in the European Union, Norway, Iceland, Australia, Switzerland, South Korea and Canada for the treatment of advanced RCC in adults who have received prior VEGF-targeted therapy, and in the European Union for previously untreated intermediate- or poor-risk advanced RCC. In March 2017, the FDA granted orphan drug designation to cabozantinib for the treatment of advanced HCC. In May 2018, the FDA accepted Exelixis' supplemental New Drug Application for CABOMETYX as a treatment for patients with previously treated HCC and assigned it a Prescription Drug User Fee Act action date of January 14, 2019. On March 28, 2018, Ipsen announced that the European Medicines Agency validated its application for a new indication for cabozantinib as a treatment for previously treated advanced HCC in the European Union; on September 20, 2018 the CHMP provided a positive opinion for CABOMETYX as a monotherapy for the treatment of HCC in adults who have been previously treated with sorafenib. In 2016, Exelixis granted Ipsen exclusive rights for the commercialization and further clinical development of cabozantinib outside of the United States and Japan. In 2017, Exelixis granted exclusive rights to Takeda Pharmaceutical Company Limited for the commercialization and further clinical development of cabozantinib for all future indications in Japan.

U.S. Important Safety Information

- **Hemorrhage**: Severe and fatal hemorrhages have occurred with CABOMETYX. In two RCC studies, the incidence of Grade ≥ 3 hemorrhagic events was 3% in CABOMETYX-treated patients. Do not administer CABOMETYX to patients that have or are at risk for severe hemorrhage.
- **Gastrointestinal (GI) Perforations and Fistulas:** In RCC studies, fistulas were reported in 1% of CABOMETYX-treated patients. Fatal perforations occurred in patients treated with CABOMETYX. In RCC studies, gastrointestinal (GI) perforations were reported in 1% of CABOMETYX-treated patients. Monitor patients for symptoms of fistulas and perforations, including abscess and sepsis. Discontinue CABOMETYX in patients who experience a fistula which cannot be appropriately managed or a GI perforation.
- **Thrombotic Events:** CABOMETYX treatment results in an increased incidence of thrombotic events. In RCC studies, venous thromboembolism occurred in 9% (including 5% pulmonary embolism) and arterial thromboembolism occurred in 1% of CABOMETYX-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, including hypertensive crisis. In RCC studies, hypertension was reported in 44% (18% Grade ≥ 3) of

CABOMETYX-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:** In RCC studies, diarrhea occurred in 74% of patients treated with CABOMETYX. Grade 3 diarrhea occurred in 11% of patients treated with CABOMETYX. 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.
- **Palmar-Plantar Erythrodysesthesia (PPE):** In RCC studies, palmar-plantar erythrodysesthesia (PPE) occurred in 42% of patients treated with CABOMETYX. Grade 3 PPE occurred in 8% of patients treated with CABOMETYX. Withhold CABOMETYX in patients who develop intolerable Grade 2 PPE or Grade 3 PPE until improvement to Grade 1; resume CABOMETYX at a reduced dose.
- **Reversible Posterior Leukoencephalopathy Syndrome (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** may be associated with CABOMETYX. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during CABOMETYX treatment and for 4 months after the last dose.
- **Adverse Reactions:** The most commonly reported (≥25%) adverse reactions are: diarrhea, fatigue, nausea, decreased appetite, hypertension, PPE, weight decreased, vomiting, dysgeusia, and stomatitis.
- **Strong CYP3A4 Inhibitors**: If concomitant use with strong CYP3A4 inhibitors cannot be avoided, reduce the CABOMETYX dosage.
- **Strong CYP3A4 Inducers:** If concomitant use with strong CYP3A4 inducers cannot be avoided, increase the CABOMETYX dosage.
- **Lactation:** Advise women not to breastfeed while taking CABOMETYX and for 4 months after the final dose.
- **Hepatic Impairment:** In patients with mild to moderate hepatic impairment, reduce the CABOMETYX dosage. CABOMETYX is not recommended for use in patients with severe hepatic impairment.

Please see accompanying full Prescribing Information
https://cabometyx.com/downloads/CABOMETYXUSPI.pdf.

About Exelixis

Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model genetic systems, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. We discovered our three commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib) and COTELLIC® (cobimetinib), and have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing our existing therapeutic assets with targeted business development activities and internal drug discovery - all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. In July 2018, Exelixis was added to the Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. For more information about Exelixis, please visit www.exelixis.com, follow @ExelixisInc on Twitter or like Exelixis, Inc. on Facebook.

Forward-Looking Statement Disclaimer

This press release contains forward-looking statements, including, without limitation, statements related to: the planned presentation of data from clinical trials of cabozantinib at the ESMO 2019 Congress; the potential of cabozantinib to treat a range of difficult-to-treat cancers; and Exelixis' plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and 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; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; the potential failure of the combination of cabozantinib and atezolizumab to demonstrate safety and/or efficacy in COSMIC-021; uncertainties inherent in the product development process; the costs of conducting clinical trials, including the ability or willingness of Exelixis' collaboration partners to invest in the resources necessary to complete the trials, as well as Exelixis' dependence on third-party vendors for the development, manufacture and supply of cabozantinib; Exelixis' ability to protect its intellectual property rights; market competition; changes in economic and business conditions; and other

factors affecting Exelixis and its development programs discussed under the caption “Risk Factors” in Exelixis’ Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 1, 2018, and in Exelixis’ future filings with the SEC. All forward-looking statements in this press release are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein.

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