Cabozantinib to Be Featured in 15 Presentations at ASCO 2018 Annual Meeting

April 26, 2018

– Cabozantinib data in a range of tumor types, including advanced hepatocellular carcinoma and advanced renal cell carcinoma, to be presented at ASCO –

– Follow-up data from the phase 1 trial of cabozantinib in combination with nivolumab with or without ipilimumab in metastatic genitourinary cancers to be highlighted –

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 26, 2018-- Exelixis, Inc. (NASDAQ:EXEL) today announced that data from clinical trials of cabozantinib will be the subject of 15 presentations at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting in Chicago, June 1-5, 2018.

Poster presentations will include detailed subset results from the CELESTIAL phase 3 pivotal trial in advanced hepatocellular carcinoma (HCC) comparing outcomes by age and in patients whose only prior treatment was sorafenib. CELESTIAL was the basis for Exelixis' supplemental New Drug Application filed with the U.S. Food and Drug Administration for CABOMETYX® (cabozantinib) tablets as a treatment for patients with previously treated advanced HCC. Additionally, longer follow-up data from the phase 1 trial of cabozantinib in combination with nivolumab with or without ipilimumab in patients with metastatic genitourinary cancers will be featured, along with preliminary safety and efficacy data on cabozantinib plus nivolumab in patients with metastatic urothelial carcinoma refractory to checkpoint inhibitor therapy.

"We're excited about the potential of cabozantinib, both alone and in combination with other therapies, across a range of difficult-to-treat cancers and look forward to presenting data from our clinical trials in genitourinary cancers, advanced hepatocellular carcinoma and other tumor types," said Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer, Exelixis. "Our data at ASCO underscore our dedication to maximizing results and expanding possibilities for people living with many different cancer types."

Cabozantinib to be featured in 15 presentations
The full schedule of cabozantinib presentations expected at the meeting is as follows:

Poster Discussion

[Abstract 4019] "Cabozantinib (C) versus Placebo (P) in Patients (pts) with Advanced Hepatocellular Carcinoma (HCC) who have Received Prior Sorafenib: Results from the Randomized Phase 3 CELESTIAL Trial"
Ghassan K. Abou-Alfa, M.D., Memorial Sloan Kettering Cancer Center
Session: Gastrointestinal (Noncolorectal) Cancer
Poster presented Sunday, June 3, 8:00 – 11:30 a.m., CDT, Hall A
Discussed at the Poster Discussion Session on Sunday, June 3, 4:45 – 6:00 p.m., CDT, Hall D2

Poster Presentations

[Abstract 4528] "Clinical Efficacy Of Cabozantinib Plus Nivolumab (CaboNivo) and CaboNivo Plus Ipilimumab (CaboNivoIpi) in Patients (pts) with Chemotherapy-refractory Metastatic Urothelial Carcinoma (mUC) either Naïve (n) or Refractory (r) to Checkpoint Inhibitor (CPI)"
Rosa Maria Nadal, M.D., M.D., Ph.D., National Cancer Institute, National Institutes of Health
Session: Genitourinary (Nonprostate) Cancer
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract 4556] "Quality-Adjusted Time without Symptoms or Toxicity (Q-TWiST): Analysis of Cabozantinib (Cabo) vs Sunitinib (Sun) in Patients with Advanced Renal Cell Carcinoma (aRCC) of Intermediate or Poor Risk (Alliance A031203)"
Ronald C. Chen, M.D., MPH, University of North Carolina at Chapel Hill
Session: Genitourinary (Nonprostate) Cancer
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract 4579] "Cabozantinib (Cabo) in Advanced Non-clear Cell Renal Cell Carcinoma (nccRCC): A Retrospective Multicenter Analysis"
Nieves Martinez Chanza, Dana-Farber Cancer Institute
Session: Genitourinary (Nonprostate) Cancer
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract TPS4593] "A Phase I-II Study to Evaluate Safety and Efficacy of the Combination of Niraparib plus Cabozantinib in Patients with Advanced Kidney/Urothelial Carcinoma"
Daniel E. Castellano, M.D., Hospital 12 de Octubre
Session: Genitourinary (Nonprostate) Cancer
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract TPS4598] "A Phase 3, Randomized, Open-Label Study of Nivolumab Combined with Cabozantinib vs Sunitinib in Patients with

Previously Untreated Advanced or Metastatic Renal Cell Carcinoma (RCC; CheckMate 9ER)"
Toni K. Choueiri, M.D., Dana-Farber Cancer Institute
Session: Genitourinary (Nonprostate) Cancer
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract TPS4601] "CANTATA: A Randomized Phase 2 Study of CB-839 in Combination with Cabozantinib vs. Placebo with Cabozantinib in Patients with Advanced/Metastatic Renal Cell Carcinoma"
Nizar M. Tannir, M.D., FACP, The University of Texas MD Anderson Cancer Center
Session: Genitourinary (Nonprostate) Cancer
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract TPS4603] "CABOPRE: Phase II Study of Cabozantinib Prior to Cytoreductive Nephrectomy (CN) in Locally Advanced and/or Metastatic Renal Cell Carcinoma (mRCC)"
Guillermo de Velasco, M.D., Ph.D., Department of Medical Oncology, University Hospital 12 de Octubre, i + 12, Madrid, Spain
Session: Genitourinary (Nonprostate) Cancer
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract 1026] "A Phase II Study of Cabozantinib (Cabo) Alone or in Combination with Trastuzumab (T) in Patients (pts) with Breast Cancer Brain Metastases (BCBM)"
Jose Pablo Leone, M.D., Dana-Farber Cancer Institute
Session: Breast Cancer – Metastatic
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract TPS1119] "A Phase II Study of Nivolumab in Combination with Cabozantinib for Metastatic Triple-Negative Breast Cancer (mTNBC)"
Romualdo Barroso-Sousa, M.D., Ph.D., Dana-Farber Cancer Institute
Session: Breast Cancer – Metastatic
Poster presented Saturday, June 2, 8:00 – 11:30 a.m. CDT, Hall A

[Abstract 6088] "A Phase II Trial of Cabozantinib (CABO) for the Treatment of Radioiodine (RAI)-Refractory Differentiated Thyroid Carcinoma (DTC) in the First-line Setting"
Marcia S. Brose, M.D., Ph.D., Department of Otorhinolaryngology, Head and Neck Surgery and the Abramson Cancer Center of the University of Pennsylvania
Session: Head and Neck Cancer
Poster presented Saturday, June 2, 1:15 – 4:45 p.m. CDT, Hall A

[Abstract 3555] "A Phase I/II Trial of Cabozantinib (C) with or without Panitumumab (P) in Patients (pts) with RAS Wild-Type (WT) Metastatic Colorectal Cancer (mCRC): Clinical Outcomes in Pts with *MET* Amplification (amp) Detected in Blood"
Jingquan Jia, M.D., Ph.D., Duke University Medical Center
Session: Gastrointestinal (Colorectal) Cancer
Poster presented Sunday, June 3, 8:00 – 11:30 a.m., CDT, Hall A

[Abstract 4088] "Outcomes in Patients (pts) who had Received Sorafenib (S) as the Only Prior Systemic Therapy in the Phase 3 CELESTIAL Trial of Cabozantinib (C) versus Placebo (P) in Advanced Hepatocellular Carcinoma (HCC)"
Robin Kate Kelley, M.D., University of California San Francisco
Session: Gastrointestinal (Noncolorectal) Cancer
Poster presented Sunday, June 3, 8:00 – 11:30 a.m., CDT, Hall A

[Abstract 4090] "Outcomes Based on Age in the Phase 3 CELESTIAL Trial of Cabozantinib (C) versus Placebo (P) in Patients (pts) with Advanced Hepatocellular Carcinoma (HCC)"
Lorenza Rimassa, M.D., Humanitas Clinical and Research Center
Session: Gastrointestinal (Noncolorectal) Cancer
Poster presented Sunday, June 3, 8:00 – 11:30 a.m., CDT, Hall A

[Abstract TPS4157] "A Phase II Trial of Cabozantinib and Erlotinib for Patients with EGFR and c-MET Co-expressing Metastatic Pancreatic Adenocarcinoma"
Olumide B. Gbolahan, MBBS, Indiana University School of Medicine
Session: Gastrointestinal (Noncolorectal) Cancer
Poster presented Sunday, June 3, 8:00 – 11:30 a.m., CDT, Hall A

About the CELESTIAL Study
CELESTIAL is a randomized, double-blind, placebo-controlled study of cabozantinib in patients with advanced HCC conducted at more than 100 sites globally in 19 countries. The trial was designed to enroll 760 patients with advanced HCC who received prior sorafenib and may have received up to two prior systemic cancer therapies for HCC and had adequate liver function. Enrollment of the trial was completed in September 2017. Patients were randomized 2:1 to receive 60 mg of cabozantinib once daily or placebo and were stratified based on etiology of the disease (hepatitis C, hepatitis B or other), geographic region (Asia versus other regions) and presence of extrahepatic spread and/or macrovascular invasion (yes or no). No cross-over was allowed between the study arms during the blinded treatment phase of the trial. The primary endpoint for the trial is overall survival, and secondary endpoints include objective response rate and progression-free survival. Exploratory endpoints include patient-reported outcomes, biomarkers and safety.

About Genitourinary Cancers
Genitourinary cancers are those that affect the urinary tract, bladder, kidneys, ureter, prostate, testicles, penis or adrenal glands — parts of the body involved in reproduction and excretion — and include renal cell carcinoma (RCC) and urothelial carcinoma[1].

The American Cancer Society's 2018 statistics cite kidney cancer as among the top ten most commonly diagnosed forms of cancer among both men and women in the U.S.[2] Clear cell RCC is the most common type of kidney cancer in adults.[3] 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.[4] Approximately 30,000 patients in the U.S. and 70,000 globally require treatment.[5]

Urothelial cancers encompass carcinomas of the bladder, ureter and renal pelvis at a ratio of 50:3:1, respectively.[6] Urothelial carcinoma occurs mainly in older people; 90 percent of patients with bladder cancer are 55 years or older.[7] Bladder cancer is the fourth most common cancer in men and accounts for about five percent of all new cases of cancer in the U.S. each year.[7,8] In 2015, an estimated 708,000 people were living with bladder cancer in the U.S.[8]

About HCC
Liver cancer is the second-leading cause of cancer death worldwide, accounting for more than 700,000 deaths and nearly 800,000 new cases each year.[9] In the U.S., the incidence of liver cancer has more than tripled since 1980.[2] HCC is the most common form of liver cancer, making up about three-fourths of the estimated nearly 42,000 new cases in the U.S. in 2018. HCC is the fastest-rising cause of cancer-related death in U.S.[10] Without treatment, patients with advanced HCC usually survive less than 6 months.[11]

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 and South Korea for the treatment of advanced RCC in adults who have received prior VEGF-targeted therapy. Ipsen also submitted to the EMA the regulatory dossier for cabozantinib as a treatment for first-line advanced RCC in the European Union on August 28, 2017; on March 23, 2018, the CHMP provided a positive opinion for CABOMETYX for the first-line treatment of intermediate- or poor-risk advanced RCC. 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, including RCC.

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

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 lead compounds cabozantinib and cobimetinib, and advanced them into clinical development before entering into partnerships with leading biopharmaceutical companies in our efforts to bring these medicines to patients globally. We are steadfast in our commitment to prudently reinvest in our business to maximize the potential of our pipeline. We intend to supplement 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. Exelixis recently earned a spot on Deloitte's Technology Fast 500 list, a yearly award program honoring the 500 fastest-growing companies over the past four years. 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 at the upcoming 2018 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 1 – 5, 2018; the potential of cabozantinib, both alone and in combination with other therapies, to treat a range of difficult-to-treat cancers; 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; and Exelixis' mission to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Words such as "will," "continued," "focus," "possibilities," "potential," "intend," "expected," "future," 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; the clinical, therapeutic and commercial potential of cabozantinib; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' ability and the ability of its collaborators to conduct clinical trials of cabozantinib, both alone and in combination with other therapies, sufficient to achieve a positive completion; Exelixis' reliance upon clinical investigators; Exelixis' dependence on its relationships with its collaboration partners, including, the level of their investment in the resources necessary to successfully commercialize partnered compounds in the territories where they are approved; market acceptance of CABOMETYX, COMETRIQ, and COTELLIC and the availability of coverage and reimbursement for these products; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products; 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' annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 26, 2018, 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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