Exelixis Announces Detailed Results for Cabozantinib in Combination with Immunotherapies in Patients with Advanced Colorectal Cancer at ASCO GI 2022

January 18, 2022

– Cabozantinib in combination with atezolizumab evaluated in cohort 16 of the phase 1b COSMIC-021 trial demonstrated encouraging clinical activity with a manageable safety profile in patients with previously treated metastatic colorectal cancer –

– Cabozantinib in combination with durvalumab evaluated in cohort 2 of the phase 2 CAMILLA trial demonstrated promising efficacy and was generally well tolerated with no new safety signals in chemotherapy-refractory patients with advanced mismatch repair proficient/micro satellite stable colorectal cancer –

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 18, 2022-- Exelixis, Inc. (Nasdaq: EXEL) today announced results for cabozantinib (CABOMETYX®) in combination with immunotherapies in patients with advanced colorectal cancer, including encouraging data from cohort 16 of the phase 1b COSMIC-021 trial of cabozantinib in combination with atezolizumab in patients with metastatic colorectal cancer who were previously treated with fluoropyrimidine-containing chemotherapy. Results from cohort 2 of the phase 2 CAMILLA trial of cabozantinib in combination with durvalumab in patients with advanced mismatch repair proficient/micro satellite stable (pMMR/MSS) colorectal cancer patients who were chemotherapy-refractory were also announced. The data from these studies are being presented during Poster Session C: Cancers of the Colon, Rectum, and Anus on Saturday, January 22 at the 2022 American Society of Clinical Oncology's Gastrointestinal Cancers Symposium (ASCO GI).

Abstract 121: A phase 1b multi-tumor cohort study of cabozantinib plus atezolizumab in advanced solid tumors (COSMIC-021): Results of the colorectal cancer cohort

At a median follow-up of 28.1 months, the primary endpoint of objective response rate (ORR) by investigator per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 in cohort 16 (n=31) was 10%. The disease control rate (DCR; complete response + partial response + stable disease) was 71%. Median progression-free survival (PFS) was 3.0 months (95% confidence interval [CI]: 2.7-5.4), and median overall survival (OS) was 14.0 months (95% CI: 5.5-16.7). Median duration of response was 7.6 months (95% CI: 4.2-not estimable [NE]).

A post-hoc exploratory analysis showed that patients with wild-type RAS (n=12) had longer PFS and OS compared with patients with RAS mutations (n=19): median PFS was 5.8 months (95% CI: 2.8-11.0) compared with 2.7 months (95% CI: 1.6-4.1), respectively, and median OS was 16.7 months (95% CI: 8.4-NE) compared with 8.7 months (95% CI: 4.7-15.9), respectively. ORR was 25% for patients with wild-type RAS and 0% for patients with RAS mutations.

"Colorectal cancer is a serious disease affecting more than 150,000 people in the U.S., about a quarter of whom have metastatic disease when diagnosed," said Thomas A. Abrams, M.D., Assistant Professor of Medicine, Harvard Medical School, Senior Physician, Dana-Farber Cancer Institute, and lead investigator. "Metastatic colorectal cancer becomes more challenging to treat following disease progression on chemotherapy. Data from cohort 16 of COSMIC-021 are encouraging for clinicians and patients, as they show the potential utility of cabozantinib in combination with atezolizumab to help patients with metastatic colorectal cancer who have already progressed on at least one line of fluoropyrimidine-containing therapy."

Eligible patients had metastatic colorectal cancer with an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 and had progressed during or following systemic chemotherapy, including fluoropyrimidine plus oxaliplatin or irinotecan. Patients were allowed to have received up to two prior lines of anti-cancer therapy, including EGFR-targeted therapy. Patients with known microsatellite instability high and/or mismatch repair-deficient disease were excluded. Sixty-one percent of patients had an ECOG Performance Status of 1, 71% had received two prior lines of therapy and 94% had visceral disease, including 81% with liver metastases.

The most common treatment-related adverse events (AEs) were diarrhea (52%), fatigue (42%) and nausea (35%). Grade 3/4 treatment-related AEs occurred in 52% of patients. The most common grade 3/4 treatment-related AEs were hypertension (10%), fatigue (6%) and lipase increased (6%). No grade 5 events were reported. Six percent of patients discontinued both cabozantinib and atezolizumab due to treatment-related AEs; 6% discontinued cabozantinib only and 6% discontinued atezolizumab only.

Abstract 135: Phase II trial of cabozantinib (Cabo) plus durvalumab (Durva) in chemotherapy refractory patients with advanced mismatch repair proficient/microsatellite stable (pMMR/MSS) colorectal cancer (CRC): CAMILLA CRC cohort results

Of the 36 patients enrolled in cohort 2 of the CAMILLA trial, 29 were evaluable for the efficacy analysis. The primary outcome of investigator-assessed ORR per modified RECIST version 1.1 was 27.6%. The confirmed partial response rate was 20.7%, and the DCR was 86.2%. Median PFS was 3.8 months (95% CI: 3.4-6.3), with a 6-month PFS of 34.5% (95% CI: 17.9-54.3). Median OS was 9.1 months (95% CI: 5.8-21.8). In a subgroup analysis of those with wild-type RAS (n=12), ORR was 50.0%, and DCR was 83.3%. Median PFS was 6.3 months (95% CI: 1.8-NE), and median OS was 21.8 months (95% CI: 4.5-NE).

Patients eligible for CAMILLA cohort 2 had advanced pMMR/MSS colorectal cancer and had progressed on two or more lines of therapy. Ninety percent of patients had an ECOG Performance Score of 1, 41% had wild-type RAS and 79% had liver metastases. Approximately half (52%) of patients had received at least three prior lines of therapy.

Mismatch repair status and microsatellite instability status are considered prognostic factors in colorectal cancer and can impact treatment decisions.[1] Patients with metastatic colorectal cancer who have microsatellite stable and/or mismatch repair-proficient tumors tend to have poor responses to immune checkpoint inhibitor monotherapy, meaning alternative treatment strategies are needed.[2, 3]

Among the 36 patients evaluable for safety, the most common treatment-related AEs were grade 1/2 fatigue (53%), nausea (42%), diarrhea (36%), anorexia (31%) and hand-foot syndrome (25%). Eleven patients (31%) experienced grade 3 or higher treatment-related AEs. Grade 3 or higher immune-related AEs occurred in 16.6% of patients. One patient discontinued durvalumab due to AEs; no patients discontinued cabozantinib.

CAMILLA is an investigator-sponsored trial conducted by Anwaar Saeed, M.D., GI medical oncologist and Associate Director of the Early Phase Program at The University of Kansas Cancer Center.

“After disease progression following prior treatment, people with advanced colorectal cancer are in need of additional treatment options that can help control their disease,” said Vicki L. Goodman, M.D., Executive Vice President, Product Development and Medical Affairs, and Chief Medical Officer, Exelixis. “We are pleased that the findings from cohort 16 of COSMIC-021 and cohort 2 of CAMILLA validate the potential of cabozantinib in combination with immunotherapies in advanced colorectal cancer, as this patient community often faces poor outcomes.”

About COSMIC-021

COSMIC-021 is a multicenter, phase 1b, open-label study that is divided into two parts: a dose-escalation phase and an expansion cohort phase. The dose-escalation phase was designed to enroll patients either with advanced renal cell carcinoma (RCC) with or without prior systemic therapy or with inoperable, locally advanced, metastatic or recurrent urothelial carcinoma (UC), (including renal, pelvis, ureter, urinary bladder and urethra) after prior platinum-based therapy. Ultimately, all 12 patients who enrolled in this stage of the trial were patients with advanced RCC. The dose-escalation phase of the study determined the recommended dose of cabozantinib to be 40 mg daily when given in combination with atezolizumab (1200 mg infusion once every three weeks).

In the expansion phase, the trial is enrolling 24 cohorts in 12 tumor types: RCC, UC, non-small cell lung cancer (NSCLC), castration-resistant prostate cancer (CRPC), hepatocellular carcinoma (HCC), triple-negative breast cancer, epithelial ovarian cancer, endometrial cancer, gastric or gastroesophageal junction adenocarcinoma, colorectal adenocarcinoma, head and neck cancer and differentiated thyroid cancer.

Three of the cohorts are exploratory single agent cohorts: one enrolled 31 patients with advanced NSCLC, one has been expanded to enroll up to 80 patients with advanced CRPC to be treated with cabozantinib as a single-agent, and one enrolled 10 patients with advanced CRPC to be treated with single-agent atezolizumab. Exploratory single agent cohorts have the option to be expanded up to 80 patients (cabozantinib) and 30 patients (atezolizumab) total.

Exelixis is the study sponsor of COSMIC-021. Both Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda) have opted in to participate in the trial and are contributing to the funding for this study under the terms of the companies’ respective collaboration agreements with Exelixis. Roche is providing atezolizumab for the trial. More information on this trial is available on ClinicalTrials.gov.

About CAMILLA

CAMILLA is a phase 1b/2 study that is evaluating cabozantinib in combination with durvalumab with or without tremelimumab in patients with advanced gastroesophageal and gastrointestinal cancers. Upon completion of the phase 1b gastrointestinal basket trial, which included 30 patients, the trial was expanded to a phase 2, multicenter trial of 117 patients with four disease cohorts. Three cohorts are evaluating cabozantinib in combination with durvalumab in gastric and esophageal cancer, colorectal cancer and HCC. The fourth cohort is evaluating cabozantinib in combination with durvalumab and tremelimumab in HCC patients. Patients enrolled in cohort 2 (CRC) received cabozantinib 40 mg daily in combination with durvalumab 1500 mg infusion once every four weeks. CAMILLA is an investigator-sponsored trial; more information is available on ClinicalTrials.gov.

About Colorectal Cancer

Colorectal cancer is the third most common cancer and the third-leading cause of cancer-related deaths in the U.S. According to the American Cancer Society, about 150,000 new cases will be diagnosed and 53,000 people will die from the disease in 2022.[4] Colorectal cancer is most frequently diagnosed among people aged 65-74 and is more common in men and those of African American descent. Nearly a quarter of colorectal cancer cases are diagnosed at the metastatic stage, at which point the five-year survival rate is just 15%.[5] It has been estimated that approximately 40% of metastatic colorectal cancer cases exhibit a RAS mutation.[6]

About CABOMETYX® (cabozantinib)

In the U.S., CABOMETYX tablets are approved for the treatment of patients with advanced RCC; for the treatment of patients with HCC who have been previously treated with sorafenib; for patients with advanced RCC as a first-line treatment in combination with nivolumab; and for adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. CABOMETYX tablets have also received regulatory approvals in the European Union and additional countries and regions worldwide. In 2016, Exelixis granted Ipsen exclusive rights for the commercialization and further clinical development of cabozantinib outside of the U.S. 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. Exelixis holds the exclusive rights to develop and commercialize cabozantinib in the U.S.

CABOMETYX in combination with atezolizumab or in combination with durvalumab is not indicated for colorectal cancer.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage: Severe and fatal hemorrhages occurred with CABOMETYX. The incidence of Grade 3 to 5 hemorrhagic events was 5% in CABOMETYX patients in RCC, HCC, and DTC studies. Discontinue CABOMETYX for Grade 3 or 4 hemorrhage and prior to surgery as recommended. Do not administer CABOMETYX to patients who have a recent history of hemorrhage, including hemoptysis, hematemesis, or melena.

Perforations and Fistulas: Fistulas, including fatal cases, occurred in 1% of CABOMETYX patients. Gastrointestinal (GI) perforations, including fatal cases, occurred in 1% of CABOMETYX patients. Monitor patients for signs and symptoms of fistulas and perforations, including abscess and sepsis.

Discontinue CABOMETYX in patients who experience a Grade 4 fistula or a GI perforation.

Thrombotic Events: CABOMETYX increased the risk of thrombotic events. Venous thromboembolism occurred in 7% (including 4% pulmonary embolism) and arterial thromboembolism in 2% of CABOMETYX patients. Fatal thrombotic events occurred in CABOMETYX patients. Discontinue CABOMETYX in patients who develop an acute myocardial infarction or serious arterial or venous thromboembolic events that require medical intervention.

Hypertension and Hypertensive Crisis: CABOMETYX can cause hypertension, including hypertensive crisis. Hypertension was reported in 37% (16% Grade 3 and <1% Grade 4) of CABOMETYX patients. Do not initiate CABOMETYX in patients with uncontrolled hypertension. Monitor blood pressure regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume at a reduced dose. Permanently discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy or for hypertensive crisis.

Diarrhea: Diarrhea occurred in 62% of CABOMETYX patients. Grade 3 diarrhea occurred in 10% of CABOMETYX patients. Monitor and manage patients using antidiarrheals as indicated. Withhold CABOMETYX until improvement to ≤ Grade 1, resume at a reduced dose.

Palmar-Plantar Erythrodysesthesia (PPE): PPE occurred in 45% of CABOMETYX patients. Grade 3 PPE occurred in 13% of CABOMETYX patients. Withhold CABOMETYX until improvement to Grade 1 and resume at a reduced dose for intolerable Grade 2 PPE or Grade 3 PPE.

Hepatotoxicity: CABOMETYX in combination with nivolumab can cause hepatic toxicity with higher frequencies of Grades 3 and 4 ALT and AST elevations compared to CABOMETYX alone. Monitor liver enzymes before initiation of and periodically throughout treatment. Consider more frequent monitoring of liver enzymes than when the drugs are administered as single agents. For elevated liver enzymes, interrupt CABOMETYX and nivolumab and consider administering corticosteroids.

With the combination of CABOMETYX and nivolumab, Grades 3 and 4 increased ALT or AST were seen in 11% of patients. ALT or AST >3 times ULN (Grade ≥2) was reported in 83 patients, of whom 23 (28%) received systemic corticosteroids; ALT or AST resolved to Grades 0-1 in 74 (89%). Among the 44 patients with Grade ≥2 increased ALT or AST who were rechallenged with either CABOMETYX (n=9) or nivolumab (n=11) as a single agent or with both (n=24), recurrence of Grade ≥2 increased ALT or AST was observed in 2 patients receiving CABOMETYX, 2 patients receiving nivolumab, and 7 patients receiving both CABOMETYX and nivolumab. Withhold and resume at a reduced dose based on severity.

Adrenal Insufficiency: CABOMETYX in combination with nivolumab can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold CABOMETYX and/or nivolumab and resume CABOMETYX at a reduced dose depending on severity.

Adrenal insufficiency occurred in 4.7% (15/320) of patients with RCC who received CABOMETYX with nivolumab, including Grade 3 (2.2%), and Grade 2 (1.9%) adverse reactions. Adrenal insufficiency led to permanent discontinuation of CABOMETYX and nivolumab in 0.9% and withholding of CABOMETYX and nivolumab in 2.8% of patients with RCC.

Approximately 80% (12/15) of patients with adrenal insufficiency received hormone replacement therapy, including systemic corticosteroids. Adrenal insufficiency resolved in 27% (n=4) of the 15 patients. Of the 9 patients in whom CABOMETYX with nivolumab was withheld for adrenal insufficiency, 6 reinstated treatment after symptom improvement; of these, all (n=6) received hormone replacement therapy and 2 had recurrence of adrenal insufficiency.

Proteinuria: Proteinuria was observed in 8% of CABOMETYX patients. Monitor urine protein regularly during CABOMETYX treatment. For Grade 2 or 3 proteinuria, withhold CABOMETYX until improvement to ≤ Grade 1 proteinuria, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX in patients who develop nephrotic syndrome.

Osteonecrosis of the Jaw (ONJ): ONJ occurred in <1% of CABOMETYX patients. ONJ can manifest as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration or erosion, persistent jaw pain, or slow healing of the mouth or jaw after dental surgery. Perform an oral examination prior to CABOMETYX initiation and periodically during treatment. Advise patients regarding good oral hygiene practices. Withhold CABOMETYX for at least 3 weeks prior to scheduled dental surgery or invasive dental procedures, if possible. Withhold CABOMETYX for development of ONJ until complete resolution, resume at a reduced dose.

Impaired Wound Healing: Wound complications occurred with CABOMETYX. Withhold CABOMETYX for at least 3 weeks prior to elective surgery. Do not administer CABOMETYX for at least 2 weeks after major surgery and until adequate wound healing. The safety of resumption of CABOMETYX after resolution of wound healing complications has not been established.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic findings on MRI, can occur with CABOMETYX. Evaluate for RPLS in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

Thyroid Dysfunction: Thyroid dysfunction, primarily hypothyroidism, has been observed with CABOMETYX. Based on the safety population, thyroid dysfunction occurred in 19% of patients treated with CABOMETYX, including Grade 3 in 0.4% of patients.

Patients should be assessed for signs of thyroid dysfunction prior to the initiation of CABOMETYX and monitored for signs and symptoms of thyroid dysfunction during CABOMETYX treatment. Thyroid function testing and management of dysfunction should be performed as clinically indicated.

Hypocalcemia: CABOMETYX can cause hypocalcemia. Based on the safety population, hypocalcemia occurred in 13% of patients treated with CABOMETYX, including Grade 3 in 2% and Grade 4 in 1% of patients. Laboratory abnormality data were not collected in CABOSUN.

In COSMIC-311, hypocalcemia occurred in 36% of patients treated with CABOMETYX, including Grade 3 in 6% and Grade 4 in 3% of patients.

Monitor blood calcium levels and replace calcium as necessary during treatment. Withhold and resume at reduced dose upon recovery or permanently discontinue CABOMETYX depending on severity.

Embryo-Fetal Toxicity: CABOMETYX can cause fetal harm. Advise pregnant women and females of reproductive potential of the potential risk to a

fetus. Verify the pregnancy status of females of reproductive potential prior to initiating CABOMETYX and advise them to use effective contraception during treatment and for 4 months after the last dose.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions are:

CABOMETYX as a single agent: diarrhea, fatigue, PPE, decreased appetite, hypertension, nausea, vomiting, weight decreased, constipation.

CABOMETYX in combination with nivolumab: diarrhea, fatigue, hepatotoxicity, PPE, stomatitis, rash, hypertension, hypothyroidism, musculoskeletal pain, decreased appetite, nausea, dysgeusia, abdominal pain, cough, and upper respiratory tract infection.

DRUG INTERACTIONS

Strong CYP3A4 Inhibitors: If coadministration with strong CYP3A4 inhibitors cannot be avoided, reduce the CABOMETYX dosage. Avoid grapefruit or grapefruit juice.

Strong CYP3A4 Inducers: If coadministration with strong CYP3A4 inducers cannot be avoided, increase the CABOMETYX dosage. Avoid St. John's wort.

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed during CABOMETYX treatment and for 4 months after the final dose.

Hepatic Impairment: In patients with moderate hepatic impairment, reduce the CABOMETYX dosage. Avoid CABOMETYX in patients with severe hepatic impairment.

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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 system genetics, 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. Our discovery efforts have resulted in four commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we 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. Exelixis is a member of 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 Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the presentation of data from COSMIC-021 during a poster session at ASCO GI; the therapeutic potential of cabozantinib in combination with immunotherapies to help patients with advanced CRC; 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; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis', Roche's and AstraZeneca's continuing compliance with applicable legal and regulatory requirements; the potential failure of cabozantinib in combination with atezolizumab or in combination with durvalumab to demonstrate safety and/or efficacy in clinical testing; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating cabozantinib; the costs of conducting clinical trials, including the ability or willingness of Exelixis' collaboration partners or investigator sponsors to invest in the resources necessary to complete the trials; Exelixis' dependence on third-party vendors for the development, manufacture and supply of cabozantinib; Exelixis', Roche's and AstraZeneca's ability to protect their respective intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of CABOMETYX; changes in economic and business conditions, including as a result of the COVID-19 pandemic; 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 November 2, 2021, 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, except as required by law.

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