



Exelixis Announces Consistent Efficacy Benefits Across Subgroups of Phase 3 CheckMate -9ER Trial of CABOMETYX® (cabozantinib) in Combination with OPDIVO® (nivolumab) as a First-line Treatment for Patients with Advanced Renal Cell Carcinoma

June 4, 2021

– Efficacy benefits with recently approved combination regimen observed regardless of baseline International Metastatic Renal Cell Carcinoma Database Consortium risk status, organ site of metastases or extent of tumor burden –

– Data to be presented during the 2021 American Society of Clinical Oncology’s Annual Meeting –

ALAMEDA, Calif.--(BUSINESS WIRE)--Jun. 4, 2021-- [Exelixis, Inc.](https://www.exelixis.com) (NASDAQ: EXEL) today announced results from a post-hoc exploratory analysis demonstrating that the efficacy benefits seen in the phase 3 CheckMate -9ER trial with CABOMETYX® (cabozantinib) in combination with Bristol Myers Squibb’s OPDIVO® (nivolumab) compared with sunitinib as a first-line treatment for advanced renal cell carcinoma (RCC) were observed across analyzed subgroups, including those based on International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) risk status, site of metastases and extent of tumor burden at baseline. The data will be presented as part of the Poster Session: Genitourinary Cancer – Kidney and Bladder at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held virtually, June 4-8, 2021. All posters will be available on demand beginning at 6:00 a.m. PT on Friday, June 4.

“To inform treatment decisions, we are eager to gain a deeper understanding of how baseline disease characteristics may impact clinical outcomes for patients treated with cabozantinib in combination with nivolumab, and this analysis supports that the combination regimen may be an appropriate option in the first-line setting for a wide range of patients with renal cell carcinoma,” said Andrea Apolo, M.D., Genitourinary Malignancies Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health, who served on the study’s steering committee. “Some of the baseline characteristics, including the presence of bone metastases, are associated with worse outcomes, making it encouraging to see that the combination regimen demonstrated efficacy benefits in these patients.”

As presented at the ASCO 2021 Genitourinary Cancers Symposium (ASCO GU) in February 2021, at a median follow-up of 23.5 months in the CheckMate -9ER intent-to-treat population, median progression-free survival (PFS) was doubled at 17.0 months for CABOMETYX in combination with OPDIVO compared with 8.3 months for sunitinib (hazard ratio [HR]: 0.52; 95% confidence interval [CI]: 0.43-0.64; P<0.0001). Median overall survival (OS) was not yet reached for the combination regimen versus 29.5 months with sunitinib (HR 0.66; 95% CI: 0.50-0.87; P=0.0034). Objective response rate (ORR) was 54.8% with CABOMETYX in combination with OPDIVO versus 28.4% with sunitinib, and complete response (CR) rate was 9.3% versus 4.3%, respectively.

In this new exploratory analysis presented at ASCO 2021 (abstract #4553), patient subgroups were pre-specified based on the following baseline characteristics: IMDC risk status (favorable-, intermediate- or poor-risk disease), site of metastases (liver, bone or lung), number of organ sites with tumor lesions (one or at least two) and size of tumor lesions (less than or greater than/equal to the median). Across subgroups, median PFS was longer and ORR rates were consistently higher for patients treated with CABOMETYX in combination with OPDIVO compared with sunitinib. CR rates were higher with CABOMETYX in combination with OPDIVO versus sunitinib in most subgroups, ranging up to 16.3% for CABOMETYX in combination with OPDIVO versus 8.4% for sunitinib in the subgroup with a lower than median tumor lesion size, and 19.7% for CABOMETYX in combination with OPDIVO versus 4.4% for sunitinib in the subgroup where metastatic spread was limited to one organ site. See table below for additional details.

“Following the FDA approval of CABOMETYX in combination with OPDIVO as a first-line treatment for advanced renal cell carcinoma in January, these data further underscore the combination regimen’s role as an important option for a broad range of patients in need of first-line treatment for RCC,” said Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer, Exelixis. “Our goal is to provide this combination regimen to as many eligible patients as possible, and we’re glad to see these data support its use across RCC patients regardless of prognosis.”

Median OS was not yet reached for CABOMETYX in combination with OPDIVO in any subgroup, but 15-month OS rates were higher with CABOMETYX in combination with OPDIVO compared with sunitinib in all subgroups. Hazard ratios favored CABOMETYX in combination with OPDIVO compared with sunitinib for most subgroups (see table). Note, the trial was not powered to assess efficacy in subgroups. For certain subgroups, particularly patients with favorable risk, few events were observed in either arm.

Table

| Subgroup | Median PFS (95% CI), months | | ORR, % | | CR, % | | HR for OS (95% CI) |
|---------------------------------------|---------------------------------|--------------------|---------------------|---------------------|-------|-----|---------------------|
| | C+N* | SUN** | C+N | SUN | C+N | SUN | |
| IMDC favorable risk (n=146) | 24.7 (13.1–NE ^a) | 12.8 (9.6–18.5) | 66.2 (54.3–76.8) | 44.4 (32.7–56.6) | 9.5 | 9.7 | 0.94 (0.46-1.92) |
| IMDC intermediate risk (n=376) | 17.5 (11.3–19.4) | 8.5 (7.0–9.8) | 55.9 (48.4–63.1) | 28.7 (22.4–35.8) | 10.6 | 3.2 | 0.74 (0.50-1.08) |
| IMDC poor risk (n=129) | 9.9 (5.9–17.7) | 4.2 (2.9–5.6) | 37.7 (25.6–51.0) | 10.3 (4.2–20.1) | 4.9 | 1.5 | 0.45 (0.27-0.76) |

| | | | | | | | |
|--|---------------------|--------------------|---------------------|---------------------|------|-----|---------------------|
| Liver metastases (n=127) | 10.9 (7.0-15.2) | 5.6 (2.8-8.2) | 49.3 (37.4-61.3) | 20.4 (10.6-33.5) | 1.4 | 1.9 | 0.47 (0.27-0.82) |
| Bone metastases (n=151) | 18.2 (8.3-20.1) | 4.4 (3.7-7.0) | 48.1 (36.7-59.6) | 11.1 (4.9-20.7) | 6.3 | 0.0 | 0.64 (0.39-1.06) |
| Lung metastases (n=491) | 16.8 (11.9-19.4) | 8.2 (6.9-9.6) | 55.8 (49.3-62.2) | 29.5 (23.9-35.5) | 7.5 | 4.4 | 0.63 (0.46-0.86) |
| One organ site with tumor lesions (n=129) | 24.9 (13.1-NE) | 12.6 (8.2-19.2) | 62.3 (49.0-74.4) | 35.3 (24.1-47.8) | 19.7 | 4.4 | 0.79 (0.33-1.90) |
| Two or more organ sites with tumor lesions (n=519) | 15.3 (11.2-19.3) | 7.1 (5.9-9.2) | 53.3 (47.0-59.4) | 26.7 (21.4-32.6) | 6.9 | 4.3 | 0.63 (0.47-0.84) |
| Tumor lesion size less than the median (72.1 mm) (n=327) | 20.3 (17.7-24.9) | 9.8 (8.3-12.4) | 61.9 (53.9-69.4) | 35.9 (28.7-43.7) | 16.3 | 8.4 | 0.64 (0.38-1.06) |
| Tumor lesion size greater than or equal to the median (72.1 mm) (n=324) | 11.1 (9.0-15.6) | 6.3 (5.4-8.3) | 47.9 (40.0-55.8) | 20.5 (14.5-27.6) | 2.5 | 0.0 | 0.64 (0.46-0.89) |

*C+N: CABOMETYX (cabozantinib) in combination with OPDIVO (nivolumab)

**SUN: sunitinib

^aNot estimable

In CheckMate -9ER, CABOMETYX in combination with OPDIVO was generally well tolerated and reflected the known safety profiles of the tyrosine kinase inhibitor and immunotherapy components in previously untreated advanced RCC. The most common adverse reactions reported in at least 20% of patients treated with CABOMETYX in combination with OPDIVO were diarrhea, fatigue, hepatotoxicity, palmar-plantar erythrodysesthesia, stomatitis, rash, hypertension, hypothyroidism, musculoskeletal pain, decreased appetite, nausea, dysgeusia, abdominal pain, cough and upper respiratory tract infection. A safety analysis with extended follow-up reported at ASCO GU this year identified no new safety signals; among patients treated with OPDIVO and CABOMETYX, 6.6% discontinued both agents due to treatment-related adverse events, 9.7% discontinued OPDIVO only, and 7.2% discontinued CABOMETYX only.

About CheckMate -9ER

CheckMate -9ER is an open-label, randomized (1:1), multi-national phase 3 trial evaluating patients with previously untreated advanced or metastatic renal cell carcinoma with a clear cell component. A total of 651 patients (22% favorable risk, 58% intermediate risk, 20% poor risk; 25% PD-L1 \geq 1%) were randomized to CABOMETYX at a dose of 40 mg QD and OPDIVO (n = 323) versus sunitinib (n = 328). The primary endpoint is PFS. Secondary endpoints include OS and ORR. The primary efficacy analysis compares the doublet combination regimen of CABOMETYX and OPDIVO versus sunitinib in all randomized patients. The trial is sponsored by Bristol Myers Squibb and Ono Pharmaceutical Co. and co-funded by Exelixis, Ipsen and Takeda Pharmaceutical Company Limited.

About RCC

The American Cancer Society's 2021 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 form 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 13%.¹ Approximately 32,000 patients in the U.S. and 71,000 worldwide will require systemic treatment for advanced kidney cancer in 2021.³

About 70% of RCC cases are known as "clear cell" carcinomas, based on histology.⁴ The majority of clear cell RCC tumors have below-normal levels of a protein called von Hippel-Lindau, which leads to higher levels of MET, AXL and VEGF.^{5,6} These proteins promote tumor angiogenesis (blood vessel growth), growth, invasiveness and metastasis.^{7,8,9,10} MET and AXL may provide escape pathways that drive resistance to VEGF receptor inhibitors.^{6,7}

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 hepatocellular carcinoma who have been previously treated with sorafenib; and for patients with advanced RCC as a first-line treatment in combination with OPDIVO. 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 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. Exelixis holds the exclusive rights to develop and commercialize cabozantinib in the United States.

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 and HCC studies. Discontinue CABOMETYX for Grade 3 or 4 hemorrhage. 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 36% (17% 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. Discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy or for hypertensive crisis.

Diarrhea: Diarrhea occurred in 63% of CABOMETYX patients. Grade 3 diarrhea occurred in 11% of CABOMETYX patients. Withhold CABOMETYX until improvement to Grade 1 and resume at a reduced dose for intolerable Grade 2 diarrhea, Grade 3 diarrhea that cannot be managed with standard antidiarrheal treatments, or Grade 4 diarrhea.

Palmar-Plantar Erythrodysesthesia (PPE): PPE occurred in 44% 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.

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 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 7% of CABOMETYX patients. Monitor urine protein regularly during CABOMETYX treatment. 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.

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 is observed. 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.

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 ($\geq 20\%$) adverse reactions are:

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

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. In November 2020, the company was named to *Fortune's* 100 Fastest-Growing Companies list for the first time, ranking 17th overall and the third-highest biopharmaceutical company. 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 the phase 3 CheckMate -9ER trial at ASCO 2021; the therapeutic potential of the combination of CABOMETYX and OPDIVO in the first-line setting for a wide range of patients with RCC; Exelixis' goal to provide the combination regimen of CABOMETYX and OPDIVO to as many patents as possible; 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' and BMS' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating the combination of CABOMETYX and OPDIVO; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications and their adherence to their obligations under relevant collaboration agreements; Exelixis' dependence on third-party vendors for the development, manufacture and supply of cabozantinib; Exelixis' ability to protect its 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 May 6, 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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OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

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