# Exelixis Announces Detailed Results from Urothelial Carcinoma and Non-Small Cell Lung Cancer Cohorts of the COSMIC-021 Trial at ASCO 2022

May 26, 2022

*– Cabozantinib in combination with atezolizumab demonstrated encouraging activity with a manageable safety profile in patients with locally advanced or metastatic urothelial carcinoma and patients with previously treated advanced non-small cell lung cancer –*

ALAMEDA, Calif.--(BUSINESS WIRE)--May 26, 2022-- Exelixis, Inc. (Nasdaq: EXEL) today announced detailed results from multiple cohorts of the phase 1b COSMIC-021 trial of cabozantinib (CABOMETYX®) as a monotherapy and in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. Data from urothelial carcinoma (UC) cohorts 3, 4 and 5 and from non-small cell lung cancer (NSCLC) cohorts 7 and 20 will be presented during oral abstract sessions at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held June 3-7.

**UC Cohorts 3, 4 and 5 (abstract 4504):**

UC results will be presented by Sumanta Pal, M.D., Clinical Professor, City of Hope, and the principal investigator for the COSMIC-021 study beginning at 2:45 p.m. CT on Friday, June 3 during the Oral Abstract Session: Genitourinary Cancer – Kidney and Bladder. In these cohorts, enrolled patients had inoperable locally advanced or metastatic UC with transitional cell histology and Eastern Cooperative Oncology Group Performance Status of 0-1. Cohort 3 had not received prior systemic therapy for advanced/metastatic disease and was ineligible for cisplatin-based chemotherapy, cohort 4 had not received prior systemic therapy for advanced/metastatic disease and was eligible for cisplatin-based chemotherapy and cohort 5 had received one prior immune checkpoint inhibitor (ICI) and no prior vascular endothelial growth factor receptor (VEGFR)-tyrosine kinase inhibitor (TKI) therapy. Patients in all three cohorts received cabozantinib in combination with atezolizumab.

At a median follow-up of 27.9 months for cohort 3, 19.1 months for cohort 4 and 32.9 months for cohort 5, the primary endpoint of objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 by investigator was 20%, 30% and 10%, respectively. Cabozantinib in combination with atezolizumab demonstrated encouraging clinical activity for other endpoints and a manageable safety profile across all three cohorts. See other efficacy outcomes, the most common treatment-related adverse events (AEs) and discontinuation rates in Table 1 below.

“People with advanced bladder cancer face a poor prognosis, meaning new treatment options are needed, both in the first-line setting and after disease progression,” said Dr. Pal. “Building on previous positive results in bladder cancer from cohort 2 of COSMIC-021, the findings that the combination of cabozantinib and atezolizumab benefited multiple bladder cancer populations are encouraging for these patients and their physicians. These results, together with the newest findings from multiple COSMIC-021 lung cohorts also being presented at ASCO, underscore the broad potential of this combination regimen for patients with advanced cancers who require additional treatment options.”

| **TABLE 1** | **Cohort 3 Cisplatin ineligible (N=30)** | **Cohort 4 Cisplatin eligible (N=30)** | **Cohort 5 Received prior ICI (N=31)** |
|---|---|---|---|
| **Efficacy** | | | |
| **Objective response rate (95% CI)** | 20% (8-39) | 30% (15-49) | 10% (2-26) |
| **Disease control rate (95% CI)** | 80% (61-92) | 63% (44-80) | 61% (42-78) |
| **Median duration of response, months (95% CI)** | 7.1 (2.8-NE) | NE (7.2-NE) | 4.1 (2.6-NE) |
| **Median progression-free survival, months (95% CI)** | 5.6 (3.1-11.1) | 7.8 (1.6-13.8) | 3.0 (1.8-5.5) |
| **Median overall survival, months (95% CI)** | 14.3 (8.6-NE) | 13.5 (7.8-23.2) | 8.2 (5.5-9.8) |
| **AEs** | | | |
| **Any grade treatment-related AE, n (%)** | 29 (97) | 28 (93) | 28 (90) |
| **Diarrhea** | 13 (43) | 10 (33) | 11 (35) |
| **Aspartate aminotransferase increased** | 11 (37) | 6 (20) | 6 (19) |
| **Decreased appetite** | 10 (33) | 8 (27) | 12 (39) |
| **Alanine aminotransferase increased** | 9 (30) | 5 (17) | 5 (16) |
| **Fatigue** | 8 (27) | 8 (27) | 15 (48) |
| **Nausea** | 8 (27) | 5 (17) | 8 (26) |
| **Grade 3/4 treatment-related AE, n (%)** | 19 (63) | 13 (43) | 14 (45) |
| **Grade 5 treatment-related AE, n** | 0 | 0 | 0 |
| **Discontinuations due to treatment-related AEs, n (%)** | | | |
| **Cabozantinib** | 8 (27) | 9 (30) | 6 (19) |
| **Atezolizumab** | 5 (17) | 5 (17) | 7 (23) |
| **Both** | 4 (13) | 5 (17) | 6 (19) |

AE=adverse event; CI=confidence interval; ICI=immune checkpoint inhibitor; NE=not evaluable

**NSCLC Cohorts 7 and 20 (abstract 9005):**

Results for cohorts 7 and 20 will be presented by Joel Neal, M.D., Ph.D., Associate Professor of Medicine (Oncology), Stanford School of Medicine, beginning at 1:00 p.m. CT on Friday, June 3 during the Oral Abstract Session: Lung Cancer – Non-Small Cell Metastatic. Eligible patients had stage IV non-squamous NSCLC and had progressed on one prior ICI, with no more than two lines of prior systemic anticancer therapy, but not VEGFR-TKI therapy. Patients received either cabozantinib in combination with atezolizumab (cohort 7) or cabozantinib alone (cohort 20).

At a median follow-up of 24.7 months for cohort 7 and 21.5 months for cohort 20, the primary endpoint of ORR per RECIST version 1.1 by investigator was 19% and 6%, respectively. A manageable safety profile was seen in both cohorts. Other efficacy outcomes, the most common treatment-emergent AEs and discontinuation rates are shown in Table 2 below. In cohort 7, clinical activity was observed with cabozantinib in combination with atezolizumab irrespective of PD-L1 expression.

"We are pleased to present these promising findings of cabozantinib in combination with atezolizumab at ASCO 2022, reinforcing our longstanding commitment to advancing therapies that improve outcomes for those with advanced solid tumors," said Vicki L. Goodman, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. "We look forward to continuing research for these cancers, including through our ongoing phase 3 CONTACT-01 pivotal trial of cabozantinib in combination with atezolizumab in non-small cell lung cancer. Beyond cabozantinib, we launched the phase 1b STELLAR-001 and STELLAR-002 trials of our next-generation TKI, XL092, in combination with immunotherapies in genitourinary cancers, and we are also studying our next-generation tissue factor-targeting antibody-drug conjugate, XB002, in advanced solid tumors, including lung and bladder cancers."

**TABLE 2**

| | **Cohort 7 Cabozantinib + atezolizumab (N=81)** | **Cohort 20 Cabozantinib (N=31)*** |
|---|---|---|
| **Efficacy** | | |
| **Objective response rate (95% CI)** | 19% (11-29) | 6% (1-21) |
| **Disease control rate (95% CI)** | 80% (70-88) | 65% (45-81) |
| **Median duration of response, months (95% CI)** | 5.8 (4.2-6.9) | 10.6 (6.3-NE) |
| **Median progression-free survival, months (95% CI)** | 4.5 (3.5-5.6) | 3.4 (1.4-5.6) |
| **Median overall survival, months (95% CI)** | 13.8 (7.2-15.7) | 9.4 (4.5-11.7) |
| **AEs** | | |
| **Any grade treatment-emergent AEs, n (%)** | 81 (100) | 31 (100) |
| **Diarrhea** | 36 (44) | 16 (52) |
| **Decreased appetite** | 30 (37) | 11 (35) |
| **Fatigue** | 29 (36) | 11 (35) |
| **Nausea** | 28 (35) | 15 (48) |
| **Asthenia** | 24 (30) | 12 (39) |
| **Constipation** | 21 (26) | 5 (16) |
| **Pyrexia** | 20 (25) | 2 (6) |
| **Grade 3/4 treatment-emergent AE, n (%)** | 43 (53) | 22 (71) |
| **Grade 5 treatment-related AE, n** | 1 | 1 |
| **Discontinuations due to treatment-related AEs, n (%)** | | |
| **Cabozantinib** | 11 (14) | 3 (10) |
| **Atezolizumab** | 8 (10) | 1 (3) |
| **Both** | 5 (6) | 1 (3) |

AE=adverse event; CI=confidence interval; NE=not evaluable

*Includes 8 patients who initiated therapy with cabozantinib plus atezolizumab after experiencing disease progression.

**About COSMIC-021**

COSMIC-021 is a multicenter, phase 1b, open-label study that enrolled a total of 914 patients. The trial was 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 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 had 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 enrolled a total of 902 patients across 23 cohorts in 12 tumor types: RCC, UC, NSCLC, metastatic 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 (DTC).

Four of the cohorts were exploratory single-agent cohorts: two in advanced UC or NSCLC, one in advanced CRPC evaluating cabozantinib as a single-agent, and one in advanced CRPC evaluating single-agent atezolizumab.

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 about COSMIC-021 is available at ClinicalTrials.gov.

**About UC**

UC is the most common type of bladder cancer, accounting for 90% of all cases.[1] Bladder cancer is the sixth most common cancer in the U.S., with more than 81,000 new cases expected to be diagnosed in 2022.[2] Bladder cancer occurs mainly in older people and is more common in men.[3] Over half of cases are found at early stages, when the five-year survival rate is 96%. The five-year survival rate is only 7.7%, however, for metastatic disease.[4]

**About NSCLC**

Lung cancer is the second most common type of cancer in the U.S., with more than 236,000 new cases expected to be diagnosed in 2022. The disease is the leading cause of cancer-related mortality in both men and women, causing 25% of all cancer-related deaths. The majority (84%) of lung cancer cases are NSCLC, which mainly comprise adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[5,6] The five-year survival rate for patients with NSCLC is 26%, but that rate falls to just 7% for those with advanced or metastatic disease.[7] More than half of lung cancer cases are diagnosed at an advanced stage, and more options are needed for these patients.[8]

**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 DTC 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 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 is not indicated as a treatment for metastatic UC or NSCLC.

**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 UC and NSCLC cohorts of COSMIC-021 during oral abstract sessions at ASCO 2022; the therapeutic potential of cabozantinib in combination with atezolizumab to help patients with advanced cancers who require additional treatment options; Exelixis' longstanding commitment to advancing therapies that improve outcomes for patients with advanced solid tumors and plans to continuing research for these cancers, including NSCLC; 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 Roche'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' and Roche'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 global events; 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 10, 2022, 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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[4] Cancer Stat Facts: Bladder Cancer. SEER website. Available at: https://seer.cancer.gov/statfacts/html/urinb.html. Accessed May 2022.

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[6] What Is Lung Cancer? ACS website. Available at: https://www.cancer.org/cancer/lung-cancer/about/what-is.html. Accessed May 2022.

[7] Lung Cancer – Non-small Cell: Statistics. Cancer.Net website. https://www.cancer.org/cancer/lung-cancer/about/what-is.html. Accessed May 2022.

[8] Cancer Stat Facts: Lung and Bronchus Cancer. SEER website. Available at: https://seer.cancer.gov/statfacts/html/lungb.html. Accessed May 2022.

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