Exelixis Announces Initiation of Phase 1b Trial Evaluating XL092 in Combination with Immuno-oncology Therapies in Patients with Advanced Solid Tumors

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– STELLAR-002 is second trial to evaluate XL092, a next-generation tyrosine kinase inhibitor, in advanced cancers –

ALAMEDA, Calif.--(BUSINESS WIRE)--Dec. 15, 2021-- Exelixis, Inc. (Nasdaq: EXEL) today announced initiation of the dose-escalation stage of STELLAR-002, a phase 1b trial evaluating XL092 in combination with immuno-oncology therapies in advanced solid tumors. The objective of the study is to evaluate the safety, tolerability and efficacy of XL092, Exelixis' novel next-generation tyrosine kinase inhibitor (TKI), in combination with: nivolumab (OPDIVO®); nivolumab and ipilimumab (YERVOY®); and nivolumab and bempegaldesleukin.

Exelixis is sponsoring STELLAR-002, and Bristol-Myers Squibb Company (NYSE: BMY) is providing nivolumab, ipilimumab and bempegaldesleukin for use in the trial, in accordance with their clinical trial collaboration and supply agreement announced in June. Nektar Therapeutics (Nasdaq: NKTR) will supply bempegaldesleukin to Bristol Myers Squibb through their existing global development and commercialization collaboration.

"The initiation of the dose-escalation stage of STELLAR-002, our second phase 1b trial of XL092, is an important step toward evaluating the potential of this next-generation tyrosine kinase inhibitor in combination with three additional immuno-oncology therapies for patients with advanced genitourinary tumors," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "We are pleased to continue our successful collaboration with Bristol Myers Squibb through this trial and look forward to identifying the recommended doses for the cohort-expansion stage."

The dose-escalation stage will determine the recommended dose in patients with advanced solid tumors for each of the XL092 combination therapy regimens. Once the recommended dose is established, the trial will begin to enroll tumor-specific expansion cohorts for patients with advanced renal cell carcinoma, urothelial carcinoma and metastatic castration-resistant prostate cancer. The primary efficacy endpoint of the expansion stage will be objective response rates, except for the cohort of patients with metastatic castration-resistant prostate cancer, for which the primary endpoint will be duration of radiographic progression-free survival.

About XL092

XL092 is a next-generation oral tyrosine kinase inhibitor that targets kinases implicated in cancer growth and spread, including VEGF receptors, MET, AXL and MER. In designing XL092, Exelixis sought to build upon its extensive experience with cabozantinib, the company's flagship medicine, retaining the target profile while improving key characteristics, including pharmacokinetic half-life. XL092 is currently being developed for the treatment of advanced solid tumors, including genitourinary cancers, as a monotherapy and in combination with immune checkpoint inhibitors. XL092 is the first internally discovered Exelixis compound to enter the clinic following the company's reinitiation of drug-discovery activities.

About Genitourinary Cancers

Genitourinary cancers are those that affect the urinary tract, prostate, testicles or penis — parts of the body involved in reproduction and urine production and excretion — and include renal cell carcinoma (RCC), castration-resistant prostate cancer (CRPC) and urothelial carcinomas.[1]

- The American Cancer Society's (ACS) 2021 statistics cite kidney cancer as among the top 10 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] Papillary RCC accounts for about 15% of all renal cell cancers.[4,5] 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%.[2] Approximately 32,000 patients in the U.S. and over 71,000 worldwide will require systemic treatment for advanced kidney cancer in 2021, with nearly 15,000 patients in need of a first-line treatment in the U.S.[6]
- According to the ACS, in 2021, approximately 250,000 new cases of prostate cancer will be diagnosed, and 34,000 people will die from the disease.[2] Prostate cancer that has spread beyond the prostate and does not respond to androgen-suppression therapies — a common treatment for prostate cancer — is known as metastatic CRPC.[7] Researchers estimate that in 2020, 43,000 people were diagnosed with metastatic CRPC, which has a median survival of less than two years.[8,9,10]
- Urothelial cancers encompass carcinomas of the bladder, ureter and renal pelvis at a ratio of 50:3:1, respectively.[11] Bladder cancer occurs mainly in older people, with 90% of patients aged 55 or older.[12] With an estimated 84,000 new cases expected to be diagnosed in 2021, bladder cancer accounts for about 5% of all new cases of cancer in the U.S. each year.[2,13] It is the fourth most common cancer in men.[2]

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 clinical and therapeutic potential of XL092 in combination with immuno-oncology therapies for patients with advanced solid tumors; 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: complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' continuing compliance with applicable legal and regulatory requirements; the potential failure of the combination of XL092 and immuno-oncology therapies to demonstrate safety and/or efficacy in STELLAR-002 and in future trials; uncertainties inherent in the product development process; the continuing COVID-19 pandemic and its impact on Exelixis' research and development operations, including Exelixis' ability to initiate new clinical trials and clinical trial sites, enroll clinical trial patients, conduct trials per protocol, and conduct drug research and discovery operations and related activities; the costs of conducting clinical trials, including the ability or willingness of Exelixis' collaboration partners to invest in the resources necessary to complete the trials; Exelixis' dependence on third-party vendors for the development, manufacture and supply of XL092; Exelixis' ability to protect its intellectual property rights; market competition; changes in economic and business conditions; and other factors affecting Exelixis and its development programs discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on 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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Investors Contact:
Susan Hubbard
EVP, Public Affairs and Investor Relations
Exelixis, Inc.
(650) 837-8194
shubbard@exelixis.com

Media Contact:

Lindsay Treadway
Executive Director, Public Affairs and Advocacy Relations
Exelixis, Inc.
(650) 837-7522
ltreadway@exelixis.com

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