# Exelixis Expands Clinical Trial Collaboration and Supply Agreement with Bristol Myers Squibb to Include the Fixed-Dose Combination of Nivolumab and Relatlimab in Combination with XL092 in Phase 1b STELLAR-002 Trial

October 4, 2022

***— Agreement enables evaluation of XL092 in combination with an additional immune checkpoint inhibitor —***

ALAMEDA, Calif.--(BUSINESS WIRE)--Oct. 4, 2022-- Exelixis, Inc. (Nasdaq: EXEL) today announced the expansion of its June 2021 Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb Company (NYSE: BMY) to include the use of the fixed-dose combination of nivolumab and relatlimab in the ongoing phase 1b STELLAR-002 clinical trial (NCT05176483), which is evaluating XL092 in combination with multiple immune checkpoint inhibitors (ICIs) in advanced solid tumors. Exelixis is sponsoring STELLAR-002, and Bristol Myers Squibb will provide the fixed-dose combination of nivolumab and relatlimab in addition to nivolumab and ipilimumab for use in the trial, which is divided into two parts: a dose-escalation stage and an expansion cohort stage. The novel triplet combination of XL092 and the fixed-dose combination of nivolumab and relatlimab has the potential to be used in multiple expansion cohorts.

XL092 is Exelixis' next-generation oral tyrosine kinase inhibitor (TKI) that targets VEGF receptors, MET, AXL, MER and other kinases implicated in cancer's growth and spread. Bristol Myers Squibb's relatlimab is a lymphocyte activation gene-3 (LAG-3)-blocking antibody. LAG-3 is an inhibitory immune checkpoint expressed on the surface of T cells.

"We are pleased to expand our agreement with Bristol Myers Squibb for the STELLAR-002 trial to include the novel fixed-dose combination of nivolumab and relatlimab to evaluate the potential benefit of combining XL092 with additional immune checkpoint inhibitors," said Vicki L. Goodman, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. "By studying multiple immune checkpoint combinations, we hope to identify the most promising regimens across multiple solid tumors to use in future pivotal trials."

Enrollment and dosing in the dose-escalation portion of STELLAR-002 is ongoing. The dose-escalation stage will determine the recommended dose in patients with advanced solid tumors for each of the combination therapy regimens, including XL092 and nivolumab, XL092, nivolumab and ipilimumab, and XL092 and the fixed-dose combination of nivolumab and relatlimab.

**About XL092**

XL092 is a next-generation oral TKI that inhibits the activity of receptor tyrosine kinases implicated in cancer growth and spread, including VEGF receptors, MET, AXL and MER. These receptor tyrosine kinases are involved in both normal cellular function and in pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and resistance to multiple therapies, including ICIs. In designing XL092, Exelixis sought to build upon its extensive experience with and the target profile of cabozantinib, the company's flagship medicine, 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 ICIs. XL092 is the first internally discovered Exelixis compound to enter the clinic following the company's reinitiation of drug-discovery activities.

**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 therapeutic potential of XL092 in combination with immune checkpoint inhibitors to treat patients across multiple solid tumors; Exelixis' future development plans for XL092, including the potential to use the novel triplet combination of XL092 and the fixed-dose combination of nivolumab and relatlimab in multiple expansion cohorts in STELLAR-002, and to identify the most promising regimens across multiple solid tumors to use in future pivotal trials; 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 potential failure of the combination of XL092 and nivolumab, the triplet combination of XL092, nivolumab and ipilimumab, or the triplet combination of XL092, nivolumab and relatlimab to demonstrate safety and/or efficacy in STELLAR-002 and in future clinical testing; uncertainties inherent in the product development process; 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 costs of conducting clinical 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, 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 August 9, 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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