Exelixis In-Licenses Aurigene's Novel CDK7 Inhibitor and Files Investigational New Drug Application for Phase 1 Clinical Trial in Advanced Solid Tumors

December 7, 2020

– Phase 1 clinical trial expected to begin in Q1 2021 –

– Under the terms of the companies' agreement, Exelixis will make an option exercise payment of $12 million to Aurigene –

– Promising preclinical data support further advancement of XL102 (formerly AUR102) alone or in combination with chemotherapy –

ALAMEDA, Calif.--(BUSINESS WIRE)--Dec. 7, 2020-- Exelixis, Inc. (Nasdaq: EXEL) and Aurigene today announced that Exelixis has exercised its exclusive option for Aurigene's novel CDK7 inhibitor under the companies' July 2019 agreement. Exelixis has now assumed responsibility for the future clinical development, commercialization, and global manufacturing of the compound now known as XL102 (formerly AUR102). Exelixis also announced that it has submitted an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA) to evaluate XL102 alone or in combination therapy for the treatment of inoperable locally advanced or metastatic solid tumors. XL102 is a potent, selective, and orally bioavailable covalent inhibitor of cyclin-dependent kinase 7 (CDK7), which is an important regulator of the cellular transcriptional and cell cycle machinery. Aurigene presented positive preclinical data demonstrating that XL102 has potent anti-proliferative activity and induces cell death in a large panel of cancer cell lines at the 32nd EORTC-NCI-AACR (ENA) Symposium (Abstract 170) in October 2020.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201207005499/en/

"With single-agent and combination potential across a variety of forms of cancer, XL102 is an important addition to the growing Exelixis pipeline," said Peter Lamb, Ph.D., Executive Vice President and Chief Scientific Officer of Exelixis. "Aurigene has done an excellent job advancing the program and maintaining development timelines during a year in which global biopharmaceutical research came under pressure from COVID-19. We are excited to begin clinical development for XL102 following the FDA's recent acceptance of our IND. As we maximize the opportunity for cabozantinib, our lead medicine, we are committed to building a diversified high-value pipeline with the potential to become novel medicines that could one day help patients with cancer recover stronger and live longer."

"Exelixis' decision to in-license XL102 and file its IND with the FDA provides important validation of Aurigene's discovery and preclinical development capabilities and the value of our partnership with Exelixis overall," said Murali Ramachandra, Ph.D., Chief Executive Officer of Aurigene. "The preclinical data generated to date for XL102 demonstrate that this novel CDK7 inhibitor is orally available and has significant potential to improve care and outcomes for patients with diverse cancer indications, including breast cancer, prostate cancer, leukemia, and lymphoma. We continue to generate additional data from the other programs that are part of our partnership with Exelixis and believe that these programs will provide additional value-creating opportunities for both companies."

Under the terms of the July 2019 agreement, Exelixis made an upfront payment of $10 million for exclusive options to license three preexisting programs, including the compound now known as XL102, from Aurigene. In addition, Exelixis and Aurigene initiated three Aurigene-led drug discovery programs on mutually agreed upon targets, in exchange for additional upfront option payments of $2.5 million per program. Exelixis is also contributing research funding to Aurigene to facilitate discovery and preclinical development work on all six programs. As the programs mature, Exelixis will have the opportunity to exercise an exclusive option for each program up until the time of IND filing acceptance. If Exelixis decides to exercise an option, it will make an option exercise payment to Aurigene and assume responsibility for that program's future clinical development and commercialization including global manufacturing. To exercise its option for XL102, Exelixis will make an option exercise payment of $12 million. Once Exelixis in-licenses a program, Aurigene will be eligible for clinical development, regulatory, and sales milestones, as well as royalties on sales. Under the terms of the agreement, Aurigene retains limited development and commercial rights for India and Russia.

About Aurigene

Aurigene Discovery Technologies Limited is a development stage biotech company engaged in discovery and clinical development of novel and best-in-class therapies to treat cancer and inflammatory diseases and a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY). Aurigene is focused on precision-oncology, oral immune checkpoint inhibitors, and the Th-17 pathway. Aurigene's programs currently in clinical development include an oral ROR-gamma inhibitor AUR101 for moderate to severe psoriasis in phase 2 under a U.S. FDA IND and a PD-L1/VISTA antagonist CA-170 for non-squamous non-small cell lung cancer in phase 2b/3 in India. Additionally, Aurigene has multiple compounds at different stages of pre-clinical development. Aurigene has also partnered with several large and mid-pharma companies in the United States and Europe and has multiple programs in clinical development. For more information, please visit Aurigene's website at www.aurigene.com.

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.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' plans to initiate a phase 1 clinical trial of XL102 in the first quarter of 2021; the therapeutic potential of XL102 to improve care and outcomes for patients with diverse cancer indications; the potential for Exelixis' and Aurigene's partnership to provide additional value-creating opportunities for both companies; Exelixis' potential future financial and other obligations under the exclusive collaboration, option and license agreement with Aurigene; 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 continuing COVID-19 pandemic and its impact on Exelixis' research and development operations; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationship with Aurigene, including Aurigene's adherence to its obligations under the exclusive collaboration, option and license agreement and the level of Aurigene's assistance to Exelixis in completing clinical trials, pursuing regulatory approvals or successfully commercializing partnered compounds in the territories where they may be approved; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' and Aurigene's continuing compliance with applicable legal and regulatory requirements; Exelixis' and Aurigene's ability to protect their respective intellectual property rights; market competition; changes in economic and business conditions; and other factors affecting Exelixis and its product pipeline discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 5, 2020, 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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