Exelixis and Aurigene Announce That Promising Preclinical Data to Be Presented at the ENA Symposium Support the Clinical Development of a Novel CDK7 Inhibitor

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– Detailed characterization of an oral inhibitor of CDK7 demonstrates potent activity against multiple hematologic and solid tumor cell lines, as monotherapy and in combination with chemotherapies –

ALAMEDA, Calif.--(BUSINESS WIRE)--Oct. 9, 2020-- Exelixis, Inc. (Nasdaq: EXEL) and Aurigene Discovery Technologies Limited (Aurigene) today disclosed new preclinical data showing that AUR102 has potent anti-tumor activity in a large panel of cancer cell lines. AUR102 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. Exelixis has an exclusive option for AUR102 under its July 2019 exclusive collaboration, option and license agreement with Aurigene. The new data will be presented in a poster (Abstract 170) at the 32nd EORTC-NCI-AACR (ENA) Symposium, which is being held virtually on October 24-25, 2020.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201009005115/en/

"CDK7 plays a critical role in regulating cellular transcription and cell cycle machinery, making it an exciting target for cancer therapy," said Murali Ramachandra, Ph.D., Chief Executive Officer of Aurigene. "The data to be presented at ENA 2020 demonstrate that AUR102 effectively engages CDK7 and inhibits a key mediator of the cell cycle and transcription. The ability to inhibit CDK7 activity with an orally available therapeutic such as AUR102 holds great potential to improve care and outcomes for patients with diverse cancer indications, including breast cancer, prostate cancer, leukemia and lymphoma."

The abstract provides a summary of results from a detailed characterization of AUR102 in cancer cell lines and animal tumor models. Additional data will be presented in the poster. Key findings included in the abstract are:

- AUR102 exhibited potent anti-proliferative activity in a large panel of cell lines with induction of cell death in cell lines derived from multiple cancer types.
- The observed anti-proliferative activity correlated with cellular CDK7 target engagement and decreased levels of P-Ser5 RNAPII, a key mediator of transcription.
- AUR102 studies showed synergy when used in combination with multiple chemotherapies.
- Oral dosing with AUR102 resulted in dose-dependent anti-tumor activity, including complete tumor regression in diffuse large B-cell lymphoma, acute myeloid leukemia, and triple-negative breast cancer xenograft models.
- Inhibition of tumor growth was accompanied by complete target engagement as demonstrated in a parallel PK-PD study.
- AUR102 significantly impacts several pathways and key cancer driver and immune-response genes.

The study authors conclude that the data support clinical evaluation of AUR102 as a single agent and in combination with chemotherapies for the treatment of cancer.

"The exciting AUR102 data to be presented at ENA 2020 provide further validation of our partnering strategy, which gives us multiple opportunities to build a pipeline of best-in-class cancer therapies," said Peter Lamb, Ph.D., Executive Vice President of Scientific Strategy and Chief Scientific Officer of Exelixis. "AUR102 could be the subject of an Investigational New Drug filing later this year, which would be an important value driver for the program itself and for our collaboration with Aurigene. We commend the Aurigene team on their ongoing success in building a robust body of data supporting the broad clinical potential of AUR102."

Under the terms of the July 2019 agreement, Exelixis made an upfront payment of $10 million for exclusive options to license three preexisting programs 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 Investigational New Drug (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. 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 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 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.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' and Aurigene's plans to present preclinical data in support of the continued development of AUR102 in a poster as part of the 32nd ENA Symposium; the potential for AUR102 to improve care and outcomes for patients with diverse cancer indications, including breast cancer, prostate cancer, leukemia and lymphoma; the potential for AUR102 to be the subject of an Investigational New Drug filing later in 2020; 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 availability of data at the referenced times; 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; the continuing COVID-19 pandemic and its impact on Exelixis' research and development operations; 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 August 6, 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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