



Exelixis In-Licenses Second Anti-Cancer Compound from Aurigene Following FDA Acceptance of Investigational New Drug Application for Phase 1 Clinical Trial in Non-Hodgkin's Lymphoma

October 14, 2021

– Robust preclinical data support Exelixis' clinical development of XL114, with phase 1 trial in Non-Hodgkin's lymphoma expected to begin in the coming months –

– Exelixis will make an option exercise payment of \$10 million to Aurigene –

ALAMEDA, Calif.--(BUSINESS WIRE)--Oct. 14, 2021-- Exelixis, Inc. (Nasdaq: EXEL) and Aurigene Discovery Technologies Limited (Aurigene) today announced that Exelixis has exercised its exclusive option under the companies' [July 2019 agreement](#) to in-license XL114 (formerly AUR104), a novel anti-cancer compound that inhibits the CARD11-BCL10-MALT1 (CBM) signaling pathway, which promotes lymphocyte survival and proliferation. Exelixis has now assumed responsibility for the future clinical development, commercialization and global manufacturing of XL114. Following the U.S. Food and Drug Administration's (FDA) recent acceptance of its Investigational New Drug (IND) application, Exelixis will soon initiate a phase 1 clinical trial evaluating XL114 monotherapy in patients with Non-Hodgkin's lymphoma (NHL). At the American Association of Cancer Research Annual Meeting in April of this year, Aurigene presented preclinical data (Abstract 1266) demonstrating that XL114 exhibited potent anti-proliferative activity in a large panel of cancer cell lines ranging from hematological cancers to solid tumors with excellent selectivity over normal cells. In addition, oral dosing of XL114 resulted in significant dose-dependent tumor growth inhibition in diffuse large B-cell lymphoma (DLBCL) and colon carcinoma models.

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XL114 is the second molecule that Exelixis in-licensed from Aurigene under the companies' July 2019 collaboration, option and license agreement. Exelixis previously exercised its option to in-license XL102, a potent, selective and orally bioavailable inhibitor of cyclin-dependent kinase 7 (CDK7), from Aurigene in [December 2020](#) and initiated a phase 1 trial of XL102 as a single agent and in combination with other anti-cancer agents in patients with advanced or metastatic solid tumors in [January 2021](#).

"We are pleased that our agreement with Aurigene has generated a second promising compound that warrants advancement into clinical development and believe the collaboration will continue to play an important role in expanding our pipeline," said Peter Lamb, Ph.D., Executive Vice President, Scientific Strategy and Chief Scientific Officer, Exelixis. "XL114 has shown potent anti-proliferative activity in lymphoma cell lines that have aberrant activation of the CBM signaling pathway and may have a differentiated profile and potential as a best-in-class molecule that could improve outcomes for patients with Non-Hodgkin's lymphoma and other hematologic cancers."

XL114 was identified to have anti-proliferative activity in cell lines with constitutive activation of CBM signaling, including activated B-cell-like DLBCL (ABC-DLBCL), mantle cell lymphoma and follicular lymphoma cell lines. Further characterization of XL114 in cell-based assays demonstrated a functional role in B-cell (BCR) signaling pathways. Additionally, XL114 showed dose-dependent tumor growth inhibition in an ABC-DLBCL mouse xenograft tumor model. In preclinical development, XL114 also demonstrated a high degree of selectivity against a broad safety pharmacology panel of enzymes and receptors. While the precise molecular mechanism underlying XL114's function in repressing BCR signaling and MALT1 activation has yet to be characterized, the fatty acid-binding protein 5 (FABP5) has been identified as a prominent XL114-binding target.

"XL114 is the second molecule that Exelixis has opted to in-license under our July 2019 agreement, underscoring the significant potential of our approach to the discovery and preclinical development of innovative cancer therapies that target novel mechanisms of action," said Murali Ramachandra, Ph.D., Chief Executive Officer, Aurigene. "Exelixis has a track record of success in the clinical development and commercialization of anti-cancer therapies that provide patients with important new treatment options, and we are pleased that the continued advancement of XL114 will be supported by the company's extensive clinical, regulatory and commercialization infrastructure."

Under the terms of the July 2019 agreement, Exelixis made an upfront payment of \$10 million for exclusive options to obtain an exclusive license from Aurigene to three preexisting programs, including the compounds now known as XL102 and XL114. In addition, Exelixis and Aurigene initiated three Aurigene-led drug discovery programs on mutually agreed upon targets, in exchange for an additional upfront payment of \$2.5 million per program. The collaboration was expanded in 2021 to include three additional early discovery programs. Exelixis is also contributing research funding to Aurigene to facilitate discovery and preclinical development work on all nine programs. Exelixis may exercise its option for a program at any time up until the first IND for the program becomes effective. Having exercised options on two programs thus far (XL102 and XL114), if and when Exelixis exercises a future 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 XL114, Exelixis will make an option exercise payment to Aurigene of \$10 million. Once Exelixis exercises its option for a program, Aurigene will be eligible for clinical development, regulatory and sales milestones, as well as royalties on future potential sales of the compound. 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, NSEIFSC: DRREDDY). 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 U.S. 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, CABOMETRYX® (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](https://twitter.com/ExelixisInc) on Twitter or like [Exelixis, Inc.](https://www.facebook.com/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 evaluating XL114 monotherapy in patients with NHL; Exelixis' belief that its collaboration with Aurigene will continue to play an important role in expanding its pipeline; the therapeutic potential of XL114 to be a best-in-class molecule that could improve outcomes for patients with NHL and other hematologic cancers; Exelixis' potential future financial and other obligations under its July 2019 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 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 companies' July 2019 agreement; 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 5, 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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Source: Exelixis, Inc.