Exelixis and Sairopa Establish Exclusive Clinical Development Collaboration and Option Agreement to Develop ADU-1805, a Potentially Best-in-Class Monoclonal Antibody Targeting SIRPα

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— IND filing for ADU-1805 expected in Q1 2023, providing Exelixis with an opportunity to expand its clinical pipeline —

— ADU-1805 may have broad applicability across multiple tumor types, including solid tumors —

ALAMEDA, Calif. & ROTTERDAM, The Netherlands--(BUSINESS WIRE)--Nov. 1, 2022-- Exelixis, Inc. (Nasdaq: EXEL) and Sairopa B.V. (Sairopa) today announced that the companies have entered into an exclusive clinical development and option agreement for ADU-1805, a potentially best-in-class monoclonal antibody that targets SIRPα. SIRPα expressed on myeloid cells interacts with CD47 present on the surface of cancer cells and blocks the ability of macrophages to clear tumor cells via phagocytosis and inhibits tumor antigen presentation to T-cells. Blocking SIRPα has the potential to improve the immune system's ability to attack tumors by addressing a significant immune-suppressive component of the tumor microenvironment. ADU-1805 is active against all human alleles of SIRPα, which may allow it to address a broader patient population than other SIRPα-directed therapies. ADU-1805 has also been optimized to bind preferentially to SIRPα vs. other SIRP family members, which may enhance its ability to stimulate immune cells.

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"ADU-1805 is a promising antibody that has been carefully optimized to maximize the potential benefit of blocking the SIRPα – CD47 checkpoint, while minimizing potential toxicities and allowing for treatment of the broadest population of appropriate patients. We believe that ADU-1805 represents a differentiated and potentially best-in-class approach to this pathway," said Peter Lamb, Ph.D., Executive Vice President, Scientific Strategy and Chief Scientific Officer, Exelixis. "With an Investigational New Drug filing anticipated in the first quarter of 2023, this agreement provides an exciting opportunity to expand our clinical pipeline. There is a strong scientific rationale for blockade of this pathway in multiple solid tumor types and for combining ADU-1805 with XL092, our novel tyrosine kinase inhibitor, and with approved immune checkpoint inhibitors, further expanding the potential clinical and commercial value of ADU-1805."

"Sairopa was founded to develop a portfolio of therapeutic antibodies that modulate immune system activity to provide benefit to cancer patients. The preclinical data we have generated to date for ADU-1805 are compelling and suggest that this novel antibody has best-in-class potential, both as a single agent and in combination with other novel therapies or immune checkpoint inhibitors," said Dharminder Chahal, Managing Director, Sairopa. Commenting on the news, Gurvinder Chahal, Sairopa's Chief Business Officer, added: "With a track record of success in advancing and commercializing novel therapies in diverse oncology indications, Exelixis was our partner of choice for realizing the broad potential of ADU-1805 and achieving our shared mission to improve outcomes for patients living with cancer."

SIRPα is expressed on the surface of macrophages and other myeloid cells, which are a significant component of the tumor microenvironment and are believed to contribute to an immune-suppressive environment. SIRPα interacts with CD47 expressed on the surface of cancer cells to inhibit antibody-dependent cellular phagocytosis (ADCP), the process by which the immune system clears tumor cells that have therapeutic antibodies bound to them from the body. Inhibition of ADCP can limit the efficacy of antibody-based therapies. SIRPα blockade also enhances tumor antigen uptake induced by tumor cytotoxic approaches such as radiotherapy or chemotherapy and enhances antigen presentation, which when combined with other immune checkpoint inhibitors is believed to enhance the anti-tumor immune response. Several CD47-targeted therapies are in development and have shown clinical efficacy both as single agents and in combination with opsonizing antibodies. However, the broad expression of CD47 in healthy tissues and CD47 inactivation of T-cells has resulted in significant toxicities, including anemia and thrombocytopenia. In contrast, SIRPα has a more limited pattern of expression that excludes red blood cells and platelets and has the potential for an improved safety profile compared with anti-CD47 therapies.

Financial Considerations

Under the terms of the agreement, Exelixis will make an upfront payment to Sairopa of $40 million and an additional $70 million in near-term milestones for an option to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies, and for certain expenses to be incurred by Sairopa in conducting prespecified phase 1 clinical studies of ADU-1805 during the option period. Sairopa is eligible to receive additional success-based development milestone payments during the option period. Following the completion of the prespecified clinical studies, Exelixis has the right to exercise its option for an option exercise fee of $225 million. If Exelixis exercises the option, Sairopa is eligible to receive additional payments upon achievement of specified clinical, commercial and net sales milestones, as well as tiered royalties on net sales worldwide.

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.

About Sairopa

Sairopa B.V. is a clinical-stage company that develops novel treatments for cancer by modulating the patient's immune system. In April 2021 Sairopa acquired, backed by Van Herk Investments, a portfolio of therapeutic antibodies from Chinook Therapeutics, Inc. These antibodies were originally developed by BioNovion/Aduro Biotech Europe using the proprietary B-Select antibody platform that was also used to identify pembrolizumab (Keytruda™), BION-1301 and MK-5890 (Guelen et al., 2022). For more information about Sairopa, please visit www.sairopa.com.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' plans to file an IND for ADU-1805 in the first quarter of 2023 and belief that the agreement with Sairopa provides an exciting opportunity for Exelixis to expand its clinical pipeline; the potential for SIRPα-directed therapies to improve the immune system's ability to attack tumors, along with an improved safety profile compared with anti-CD47 therapies; the potential for ADU-1805 to be a best-in-class monoclonal antibody targeting SIRPα, with broad applicability across multiple tumor types, including solid tumors, and capability to address a broader patient population than other SIRPα-directed therapies; Exelixis' belief that combining ADU-1805 with XL092 and with approved immune checkpoint inhibitors could further expand the potential clinical and commercial value of ADU-1805; Exelixis' immediate and future financial and other obligations under the exclusive option agreement with Sairopa; 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 Sairopa, including Sairopa's adherence to its obligations under the exclusive option agreement; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' and Sairopa's continuing compliance with applicable legal and regulatory requirements; Exelixis' and Sairopa's ability to protect their respective 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 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 9, 2022, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Quarterly Report on Form 10-Q expected to be filed with the SEC on November 1, 2022. 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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