



## Exelixis and Sairopa Announce US FDA Clears Investigational New Drug Application for ADU-1805 in Patients with Advanced Solid Tumors

February 13, 2023

*– ADU-1805 is a potential best-in-class monoclonal antibody targeting SIRP $\alpha$  to block the SIRP $\alpha$ -CD47 checkpoint –*

*– Phase 1 study of ADU-1805 as a single agent and in a combination regimen in advanced solid tumors expected to begin second quarter of this year –*

ALAMEDA, Calif. & ROTTERDAM, The Netherlands--(BUSINESS WIRE)--Feb. 13, 2023-- [Exelixis, Inc.](#) (Nasdaq: EXEL) and Sairopa B.V. (Sairopa) today announced that the U.S. Food and Drug Administration (FDA) has cleared Sairopa's Investigational New Drug (IND) Application to evaluate the safety and pharmacokinetics of ADU-1805 in adults with advanced solid tumors. As a monoclonal antibody active against all human alleles of SIRP $\alpha$ , ADU-1805 has the potential to address a broader patient population than other SIRP $\alpha$ -directed therapies.

"The clearance of this Investigational New Drug Application for ADU-1805 is an exciting milestone for our expanding biologics pipeline, marking the first of many anticipated advancements we expect this year," said Vicki L. Goodman, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. "Based on its best-in-class potential and broad applicability, we look forward to learning more about ADU-1805 from the upcoming phase 1 trial across multiple tumor types, as we continue toward our goal of finding innovative solutions for patients with advanced cancers."

By blocking SIRP $\alpha$ , a significant immune-suppressive component of the tumor microenvironment, ADU-1805 has the potential to improve the immune system's ability to attack tumors. ADU-1805 has been optimized to bind preferentially to SIRP $\alpha$  compared with other SIRP family members, which may enhance its ability to stimulate immune cells.

Under the terms of the clinical development and option agreement [announced](#) in November 2022, Exelixis has the option to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRP $\alpha$  antibodies upon review of data from prespecified phase 1 clinical studies of ADU-1805 to be completed by Sairopa during the option period. This IND clearance triggers a \$35 million milestone payment to Sairopa which will be paid in the first quarter of 2023.

"Given the robust preclinical data generated, we are thrilled that ADU-1805 is now able to advance to the clinic," said Laura Lassouw-Polman, Chief Operating Officer, Sairopa. "This is an important step forward in our partnership with Exelixis to explore the potential of ADU-1805, advancing our mission to develop therapies that modulate immune system activity to improve outcomes for cancer patients."

### About Exelixis

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by bi-coastal centers of discovery and development excellence, we are rapidly evolving our product portfolio to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules, antibody drug conjugates and other biotherapeutics. This comprehensive approach harnesses decades of robust investment in our science and partnerships to advance our investigational programs and extend the impact of our flagship commercial product, CABOMETRYX<sup>®</sup> (cabozantinib). Exelixis is driven by a bold scientific pursuit to create transformational treatments that give more patients hope for the future. For information about the company and its mission to help cancer patients recover stronger and live longer, visit [www.exelixis.com](http://www.exelixis.com), follow [@ExelixisInc](#) on Twitter, like [Exelixis, Inc.](#) on Facebook and follow [Exelixis](#) on LinkedIn.

### 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<sup>™</sup>), BION-1301 and MK-5890 (Guelen et al., 2022). For more information about Sairopa, please visit [www.sairopa.com](http://www.sairopa.com).

### Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the clinical and therapeutic potential of ADU-1805, including its potential to be a best-in-class monoclonal antibody that targets SIRP $\alpha$  to block the SIRP $\alpha$ -CD47 checkpoint, a process with the potential to improve the immune system's ability to attack tumors and stimulate immune cells, as well as Exelixis' belief that ADU-1805 may address a broader patient population than other SIRP $\alpha$ -directed therapies; Exelixis' anticipation of many advancements for the ADU-1805 program during 2023, including plans to initiate a phase 1 study evaluating ADU-1805 as a single agent and in combination regimens in patients with advanced solid tumors during the second quarter of 2023; Exelixis' goal of finding innovative solutions for patients with advanced cancers; Exelixis' immediate and future financial and other obligations under its agreement with Sairopa, including a \$35 million milestone payment to Sairopa expected during the first quarter of 2023; and Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future. 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: 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; the potential failure of ADU-1805 to demonstrate safety and/or efficacy in future trials; uncertainties inherent in the product development process; the costs of conducting clinical trials;

Exelixis' and Sairopa's dependence on third-party vendors for the development, manufacture and supply of ADU-1805; 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 development programs discussed under the caption "Risk Factors" in Exelixis' Annual Report on Form 10-K submitted to the Securities and Exchange Commission (SEC) on February 7, 2023, 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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