



Exelixis to Present Positive Preclinical Data Across Its Pipeline Portfolio for Advanced Cancers at AACR 2025

March 25, 2025

– Presentations will highlight best- and/or first-in-class potential of four small molecule and biotherapeutic development candidates for investigation in patients with advanced solid tumors –

ALAMEDA, Calif.--(BUSINESS WIRE)--Mar. 25, 2025-- [Exelixis, Inc.](#) (Nasdaq: EXEL) today announced that preclinical data will be presented for four pipeline molecules at the American Association for Cancer Research (AACR) Annual Meeting 2025 taking place April 25-30 in Chicago, IL.

"We are excited to share preclinical data from four of our pipeline molecules that constitute the next phase in our commitment to the discovery and development of innovative cancer treatments," said Dana T. Aftab, Ph.D., Executive Vice President, Discovery & Translational Research, and Chief Scientific Officer, Exelixis. "The results support the advancement into clinical development of these biotherapeutics and small molecules, as well as their potential to become best- and/or first-in-class therapies with differentiated clinical profiles."

Exelixis will present preclinical data for XL495 and XL309, small molecules that have demonstrated synthetic lethality in the context of certain genetic anomalies frequently found in some tumors. Preclinical data will also be presented for the PD-L1xNKG2A-targeting bispecific antibody XB628 and the tissue factor-targeting antibody-drug conjugate XB371. Initial details about the poster presentations can be found below. Full data will be presented at the AACR Annual Meeting.

Abstract 1733: XL495 is a potent, selective, and orally bioavailable inhibitor of PKMYT1

Lead Author: Dana Gwinn, Ph.D.

Session Title: Kinase and Phosphatase Inhibitors 1

Monday, April 28, 2:00-5:00 p.m. CT

Preclinical results will be presented for XL495, a novel, potent small molecule inhibitor of PKMYT1. The inhibition of PKMYT1 is synthetically lethal in cells with genetic anomalies that lead to replication stress—a common occurrence in cancer cells but not in normal cells. Data from the analysis show XL495 has demonstrated the potential for anti-tumor activity alone and in combination with DNA-damaging agents. A phase 1 clinical [study](#) of XL495 in patients with locally advanced or metastatic solid tumors, both as monotherapy and in combination with select cytotoxic agents in tumor-specific indications, is underway.

Abstract 2936: Preclinical characterization of XB371, a novel anti-tissue factor antibody-drug conjugate

Lead Author: Kathy Gogas, Ph.D.

Session Title: Growth Factor Receptors and Other Surface Antigens as Targets for Therapy 1

Monday, April 28, 2:00-5:00 p.m. CT

This poster presentation will highlight preclinical data for XB371, an antibody-drug conjugate, constructed using Catalent's SMARTag[®] site-specific bioconjugation platform, that pairs a tissue factor-targeting antibody with a topoisomerase inhibitor payload using a novel cleavable linker. This design may offer the molecule broad applicability across tumor types and a clinically differentiated potential. Results to be presented support *in vitro* cell killing activity and *in vivo* efficacy, supporting the advancement of XB371 into clinical development. Exelixis is planning to submit an investigational new drug application to the U.S. Food and Drug Administration (FDA) for XB371 in 2025.

Abstract 5723: XL309 is a potent, selective, and orally bioavailable USP1 inhibitor active as monotherapy and in combination with PARP inhibitors or irinotecan

Lead Author: Alex Charruyer-Reinwald, Ph.D.

Session Title: PARP Inhibitors

Tuesday, April 29, 2:00-5:00 p.m. CT

Preclinical results will be presented for XL309, a potent and selective small molecule inhibitor of USP1, the inhibition of which is lethal in cells with BRCA 1/2 mutations. The findings demonstrate activity of XL309 alone or in combination with PARP or topoisomerase inhibitors. A phase 1 clinical [study](#) of XL309 as a monotherapy or in combination with olaparib in patients with advanced solid tumors is underway.

Abstract 6067: Preclinical evaluation of XB628: A novel PD-L1 x NKG2A bispecific antibody

Lead Author: Bee-Cheng Sim, Ph.D.

Session Title: Antibodies 3: Multi-Target Checkpoint Inhibitors and Immune Activators

Tuesday, April 29, 2:00-5:00 p.m. CT

Preclinical data on XB628, a first-in-class bispecific antibody that simultaneously targets PD-L1 and NKG2A, will be presented. Data from this analysis show that XB628 is efficacious in tumor cell killing *in vitro* and *in vivo*, supporting advancement of this molecule into clinical development. Earlier this month, the U.S. FDA cleared Exelixis' Investigational New Drug application for XB628.

More information about Exelixis' pipeline is available at [Exelixis.com](#).

About Exelixis

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by drug 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, CABOMETYX[®] (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, follow [@ExelixisInc](https://twitter.com/ExelixisInc) on X (Twitter), like [Exelixis, Inc.](https://www.facebook.com/Exelixis,Inc) on Facebook and follow [Exelixis](https://www.linkedin.com/company/exelixis) on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the presentation of positive preclinical data for advanced cancers at AACR 2025; the best- and/or first-in-class potential of small molecule and biotherapeutic development candidates for investigation in patients with advanced solid tumors; Exelixis' belief in the potential of these biotherapeutics and small molecules to become best- and/or first-in-class therapies with differentiated clinical profiles; Exelixis' plans to submit any investigational new drug applications to the FDA; 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: the availability of data at the referenced times; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials; the costs of conducting clinical trials; Exelixis' ability to protect their respective intellectual property rights; market competition; changes in economic and business conditions; and other factors affecting Exelixis and its development programs detailed from time to time under the caption "Risk Factors" in Exelixis' most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in Exelixis' future filings with the Securities and Exchange Commission. 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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