Exelixis Announces Preliminary Fiscal Year 2023 Financial Results, Provides 2024 Financial Guidance, and Outlines Key Priorities and Milestones for 2024

January 7, 2024

– Cabozantinib franchise achieves approximately $1.630 billion in preliminary U.S. net product revenues for fiscal year 2023 –

– Fiscal year 2024 net product revenues guidance of $1,650 million - $1,750 million; 2024 R&D expense guidance of $925 million - $975 million –

– Appointment of two new board members, Mary C. Beckerle, Ph.D., and Gail Eckhardt, M.D., with extensive drug development and corporate governance expertise –

– Implementing corporate restructuring to focus R&D resources on clinical stage and IND-enabling activities to maximize pipeline success and operational efficiency –

– Board of Directors authorized $450 million share repurchase in 2024 after successful completion of $550 million share repurchase in 2023 –

– Presentation and webcast at 2024 J.P. Morgan Healthcare Conference tomorrow, Monday, January 8th at 4:30 p.m. PT / 7:30 p.m. ET –

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 7, 2024-- Exelixis, Inc. (Nasdaq: EXEL) today announced its preliminary unaudited financial results for the fiscal year 2023, provided financial guidance for fiscal year 2024 and delivered an update on its business. Exelixis expects 2024 to be a year of pipeline progress as it advances its portfolio of promising biotherapeutics and small molecule candidates recently highlighted at its 2023 R&D Day and pursues potential near-term label expansion opportunities for CABOMETYX® (cabozantinib).

Preliminary Fiscal Year 2023 Financial Results & 2024 Financial Guidance

Exelixis is providing the following preliminary unaudited 2023 financial results and financial guidance for 2024:

	Fiscal Year 2023	Fiscal Year 2024 Guidance
Total revenues	~ $1,830 million	$1,825 million - $1,925 million
Net product revenues	~ $1,630 million	$1,650 million - $1,750 million(1)
Cost of goods sold	~ 4.5%	4% - 5%
Research and development expenses	~ $1,045 million(2)	$925 million - $975 million(3)
Selling, general and administrative expenses	~ $545 million(4)	$425 million - $475 million(5)
Effective tax rate	n/a(6)	20% - 22%

(1) Exelixis' 2024 net product revenues guidance range includes the impact of a U.S. wholesale acquisition cost increase of 2.2% for both CABOMETYX® and COMETRIQ® effective on January 1, 2024.
(2) Includes $34 million of non-cash stock-based compensation expense.
(3) Includes $40 million of non-cash stock-based compensation expense.
(4) Includes $72 million of non-cash stock-based compensation expense.
(5) Includes $60 million of non-cash stock-based compensation expense.
(6) Preliminary results not yet available.

The preliminary 2023 financial information presented in this press release has not been audited and is subject to change. The complete Exelixis Fourth Quarter and Fiscal Year 2023 Financial Results are planned for release after market on Tuesday, February 6, 2024.

"Supported by strong revenues from cabozantinib, our global oncology franchise, Exelixis is advancing an innovative pipeline of differentiated product candidates that can improve standards of care for cancer patients," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "Our 2024 plans include filing data-driven label expansions for CABOMETYX, accelerating the development of zanzalintinib, XB002, and XL309, and moving three promising preclinical programs into clinical development. The success of our internal drug discovery efforts as highlighted at our recent R&D Day compels a rebalancing of our investment priorities from early-stage research to product development activities. Exelixis will therefore implement a corporate restructuring that will concentrate R&D resources to advance our emerging pipeline, and maintain positive cash flow to support an additional $450 million share repurchase following successful completion of the $550 million share repurchase in 2023. We are taking these steps with the conviction that they are necessary for our continued progress toward the company's goal of delivering an innovative pipeline of biotherapeutics and small molecules to help patients with cancer and create value for all of our stakeholders."

Corporate Updates

Corporate Restructuring to Rebalance Resources to Drive Pipeline Success: Exelixis will implement a corporate restructuring that will prioritize the advancement of the company's deep pipeline of clinical and near-clinical programs. As a result, Exelixis is reducing its workforce by approximately 175 employees or 13 percent. Exelixis expects to substantially complete the restructuring in the first quarter of 2024 and recognize a restructuring

charge of approximately $25 million.

Appointment of Two New Board Members: As part of the company's continued board refreshment plan announced last year, Exelixis is announcing two new appointments to its Board of Directors, effective January 5, 2024:

Mary C. Beckerle, Ph.D., Chief Executive Officer of the Huntsman Cancer Institute and Distinguished Professor of Biological and Oncological Sciences at the University of Utah. Since 2006, Dr. Beckerle has had responsibility for the vision, strategic direction, and management of the University's oncology programs, including research, care, education, and community outreach. A noted cell biologist and cancer researcher, Dr. Beckerle's work on cytoskeletal dynamics and cell adhesion has led to important advances both in basic and translational science. In addition to Exelixis, Dr. Beckerle serves as an independent director of Johnson & Johnson and Huntsman Corporation.

Gail Eckhardt, M.D., Associate Dean of Experimental Therapeutics at Baylor College of Medicine and Associate Director of Translational Research at the College's Dan L. Duncan Comprehensive Cancer Center. Dr. Eckhardt is a recognized leader in translational medicine relative to oncology with a particular emphasis on preclinical and early clinical development of molecularly targeted therapies and combination regimens to treat colorectal and other gastrointestinal cancers. She currently serves on the Board of Syros Pharmaceuticals, and as an academic advisor for eleven NCI-designated Cancer Centers, among other roles.

In addition, current Exelixis board member Alan M. Garber, M.D., Ph.D., has notified the company that he will not stand for reelection at the company's 2024 Annual Meeting of Stockholders later this spring due to his expanded responsibilities at Harvard University. Having served as Harvard's provost and chief academic officer since 2011, last week Dr. Garber became the University's interim president.

Announcement of $450 Million Share Repurchase Program for 2024: The Exelixis Board of Directors authorized the repurchase of up to an additional $450 million of the company's common stock in 2024. As of the end of 2023, Exelixis completed the repurchase of 26.2 million shares of the company's common stock, or 8% of shares outstanding, for a total of $550 million, fulfilling its commitments under the 2023 Share Repurchase Program announced in March 2023. Share repurchases under the 2024 program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination of such methods. The timing and amount of any share repurchases under the share repurchase program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of Exelixis' common stock and general market conditions.

Anticipated 2024 Cabozantinib Milestones

Cabozantinib Pivotal Trial Data Readouts and Anticipated U.S. Regulatory Filings: Detailed data from CONTACT-02, the phase 3 pivotal trial evaluating the combination of cabozantinib and atezolizumab versus a second novel hormonal therapy (NHT) in patients with metastatic castration-resistant prostate cancer (mCRPC) and measurable, extrapelvic soft tissue disease who have been previously treated with one NHT, will be the subject of an oral presentation at the American Society of Clinical Oncology 2024 Genitourinary Cancers Symposium on January 25, 2024. Positive top-line results indicating that the trial met one of its primary endpoints of progression-free survival (PFS) were announced in August 2023, and the study continues toward the next analysis of the second primary endpoint of overall survival (OS), which is anticipated in 2024. Exelixis will continue its discussions with the U.S. Food and Drug Administration (FDA) on a potential regulatory path forward for cabozantinib in mCRPC. Also anticipated in 2024 is a potential regulatory filing for cabozantinib in advanced neuroendocrine tumors (NET) based on positive results from the pivotal phase 3 CABINET study, which evaluates cabozantinib versus placebo in patients with either advanced pancreatic NET (pNET) or extra-pancreatic NET (epNET) and is conducted by The Alliance for Clinical Trials in Oncology (The Alliance). Detailed data presented at the European Society for Medical Oncology Congress 2023 showed that the study met its primary endpoint, demonstrating dramatic improvement in PFS for patients treated with cabozantinib in both the pNET and epNET cohorts. Exelixis is working with The Alliance to discuss a potential regulatory filing with the FDA and will provide an update when appropriate.

Anticipated Outcome of Cabozantinib Abbreviated New Drug Application (ANDA) Litigation with MSN Pharmaceuticals: The second bench trial for Exelixis' ongoing ANDA lawsuit against MSN Pharmaceuticals, Inc. concluded in October 2023, and Exelixis anticipates a ruling from the United States District Court for the District of Delaware in the first half of 2024. Exelixis is confident in its cabozantinib patent estate and is vigorously defending the patents at issue.

Upcoming Development Milestones

Zanzalintinib Clinical Progress Anticipated in 2024: Zanzalintinib is a third-generation tyrosine kinase inhibitor (TKI) that Exelixis believes can become the vascular endothelial growth factor receptor TKI of choice as solid tumor therapeutic landscapes continue to evolve. Exelixis is executing on three ongoing pivotal trials of zanzalintinib, STELLAR-303, -304, and -305, in forms of colorectal cancer, non-clear cell renal cell carcinoma, and squamous cell carcinoma of the head and neck, respectively. Zanzalintinib is also the subject of three ongoing earlier-stage trials, STELLAR-001, -002, and -009, intended to evaluate its potential in best-in-class combinations and identify indications for future pivotal trials, with priorities defined by emerging data and potential clinical co-funding opportunities.

XB002 Clinical Progress Anticipated in 2024: XB002 is a next-generation tissue factor (TF)-targeting antibody-drug conjugate (ADC) that Exelixis believes has development potential as a monotherapy and in combination regimens. In 2024, Exelixis is focused on advancing JEWEL-101, the phase 1 study of XB002 alone and in combination with immunotherapy in a variety of solid tumor settings with the goal of prioritizing sensitive tumor types for full development.

XL309 Clinical Progress Anticipated in 2024: XL309 is a potentially best-in-class small molecule inhibitor of USP1, which has emerged as a synthetic lethal target in the context of BRCA-mutated tumors. Exelixis in-licensed XL309 from Insilico Medicine in September 2023, and the process of transferring stewardship of the program's ongoing phase 1 trial to Exelixis was completed in the fourth quarter of 2023. Exelixis' clinical development priorities for XL309 include accelerating its development as a potential therapy for tumors that have become refractory to PARP inhibitor (PARPi) therapy, including forms of ovarian, breast, and prostate cancers, pursuing potential PARPi combinations, and moving beyond the PARPi market into new areas.

Anticipated Discovery Milestones

Three Potential Investigational New Drug (IND) Applications in 2024: Exelixis anticipates moving three programs into clinical development this

year, including two biotherapeutics and one small molecule compound. The company expects to file an IND application for the XB010 5T4-MMAE ADC program in the first half of 2024, and expects to file IND applications for the XB628 PD-L1-NKG2A bispecific antibody and XL495 small molecule PKMYT1 inhibitor programs in the second half of 2024 if preclinical data continue to be supportive.

Current Development Candidate (DC) Programs and New DC Designations expected in 2024: Exelixis has two DC programs that may be the subjects of IND filings in 2025, including the XB371 TF-Topoisomerase I inhibitor ADC and XB064 ILT-2 monoclonal antibody programs, and the XB033 IL13Ra2-Topoisomerase I inhibitor ADC that may be the subject of an IND filing in 2026. In 2024, the company expects to designate two new programs to DC status, including a small molecule PLK4 inhibitor and an additional ADC.

Presentation and Webcast

Exelixis President and Chief Executive Officer Michael M. Morrissey, Ph.D., will provide a corporate overview and discuss the company's preliminary fiscal year 2023 financial results, 2024 financial guidance, and key priorities and milestones for 2024 during the company's presentation at the 42 nd Annual J.P. Morgan Healthcare Conference beginning at 4:30 p.m. PT / 7:30 p.m. ET on Monday, January 8, 2024.

To access the webcast link, log onto www.exelixis.com and proceed to the Event Calendar page under the Investors & News heading. A replay will also be available at the same location for at least 30 days.

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 on X (Twitter), like Exelixis, Inc. on Facebook and follow Exelixis on LinkedIn.

Forward-Looking Statements and Preliminary Financial Results

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' expectation that 2024 will be a year of pipeline progress as it advances its portfolio of promising biotherapeutics and small molecule candidates and pursues potential near-term label-expansion opportunities for CABOMETYX; Exelixis' 2024 financial guidance; Exelixis' 2024 plans for filing data-driven label expansions for CABOMETYX, accelerating the development of zanzalintinib, XB002 and XL309, and moving three promising preclinical programs into clinical development; Exelixis' plans and expectations for corporate restructuring in the first quarter of 2024 and for a new $450 million share repurchase program in 2024; Exelixis' anticipated cabozantinib milestones for 2024, including the presentation of data from CONTACT-02 at ASCO GU later in January 2024, the next analysis of OS data from CONTACT-02, continued discussions with the FDA regarding the potential regulatory path forward for cabozantinib in mCRPC, a potential regulatory filing in 2024 for cabozantinib as a treatment for NET based on positive results from CABINET, and an expected ruling in the ANDA lawsuit against MSN Pharmaceuticals, Inc. in the first half of 2024; Exelixis' upcoming development milestones for 2024, including clinical progress and priorities for zanzalintinib and Exelixis' belief that zanzalintinib can become the vascular endothelial growth factor receptor TKI of choice as solid tumor therapeutic landscapes continue to evolve, clinical progress and priorities for XB002 and Exelixis' belief that XB002 has development potential as a monotherapy and in combination regimens, and clinical progress and priorities for XL309 and Exelixis' belief that XL309 is a potentially best-in-class small molecule inhibitor of USP1; Exelixis' anticipated discovery milestones for 2024, including potential IND filings for XB010 in the first half of 2024 and for XB628 and XL495 in the second half of 2024 if preclinical data continue to be supportive, and the designation of two new programs to DC status in 2024, as well as potential IND filings in 2025 for XB371 and XB064; Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future; and other statements that are not historical facts. 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 degree of market acceptance of CABOMETYX and other Exelixis products in the indications for which they are approved and in the territories where they are approved, and Exelixis' and its partners' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX and other Exelixis products in comparison to competing products; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' ability to maintain and scale adequate sales, marketing, market access and product distribution capabilities for its products or to enter into and maintain agreements with third parties to do so; the availability of data at the referenced times; the potential failure of cabozantinib, zanzalintinib and other Exelixis product candidates, both alone and in combination with other therapies, to demonstrate safety and/or efficacy in clinical testing; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications, their adherence to their obligations under relevant collaboration agreements and the level of their investment in the resources necessary to complete clinical trials or successfully commercialize partnered compounds in the territories where they are approved; 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 evaluating cabozantinib and other Exelixis product candidates; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products and product candidates; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; changes in economic and business conditions; and other factors 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' other 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.

In addition, this press release includes Exelixis' preliminary financial results for the fiscal year ended December 29, 2023. Exelixis is currently in the process of finalizing its financial results for the quarter and fiscal year ended December 29, 2023, and the preliminary financial results presented in this press release are based only upon preliminary information available to Exelixis as of January 7, 2024. Exelixis' preliminary financial results should not

be viewed as a substitute for audited financial statements prepared in accordance with U.S. GAAP, and undue reliance should not be placed on Exelixis' preliminary financial results. Exelixis' independent registered public accounting firm has not audited or reviewed the preliminary financial results included in this press release or expressed any opinion or other form of assurance on such preliminary financial results. In addition, items or events may be identified or occur after the date of this press release due to the completion of operational and financial closing procedures, final audit adjustments and other developments may arise that would require Exelixis to make material adjustments to the preliminary financial results included in this press release. Therefore, the preliminary financial results included in this press release may differ, perhaps materially, from the financial results that will be reflected in Exelixis' audited consolidated financial statements for the fiscal year ended December 29, 2023.

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Source: Exelixis, Inc.