Exelixis Announces Preliminary Fiscal Year 2024 Financial Results, Provides 2025 Financial Guidance and Outlines Key Priorities and Milestones for 2025

January 12, 2025

– Cabozantinib franchise achieves approximately $1.805 billion in preliminary U.S. net product revenues for fiscal year 2024 –

– Fiscal year 2025 net product revenues guidance of $1.95 billion - $2.05 billion –

– Presentation and webcast at 43rd Annual J.P. Morgan Healthcare Conference tomorrow, Monday, January 13th at 5:15 p.m. PT / 8:15 p.m. ET –

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 12, 2025-- Exelixis, Inc. (Nasdaq: EXEL) today announced its preliminary unaudited financial results for the fiscal year 2024, provided financial guidance for fiscal year 2025 and delivered an update on its business. Exelixis anticipates 2025 will be a year of clinical and regulatory execution and continued growth for its cabozantinib franchise, as well as multiple data readouts for zanzalintinib and across its diversified pipeline of small molecules and biotherapeutics with the potential to improve standards of care for patients with cancer.

Preliminary Fiscal Year 2024 Financial Results & 2025 Financial Guidance

Exelixis is providing the following preliminary unaudited 2024 financial results and financial guidance for 2025. Net product and total revenues guidance do not currently reflect any revenues resulting from a potential U.S. regulatory approval and commercial launch of CABOMETYX® (cabozantinib) for the treatment of patients with previously treated advanced neuroendocrine tumors (NET). The U.S. Food and Drug Administration (FDA) is currently reviewing Exelixis' supplemental New Drug Application (sNDA) for this proposed indication, with a Prescription Drug User Fee Act (PDUFA) target action date of April 3, 2025.

	Fiscal Year 2024	Fiscal Year 2025 Guidance
Total revenues	~ $2.165 billion	$2.15 billion - $2.25 billion
Net product revenues	~ $1.805 billion	$1.95 billion - $2.05 billion(1)
Cost of goods sold	~ 4.2%	4% - 5% of net product revenues
Research and development expenses	~ $910 million(2)	$925 million - $975 million(3)
Selling, general and administrative expenses	~ $495 million(4)	$475 million - $525 million(5)
Effective tax rate	n/a(6)	21% - 23%
Ending cash and marketable securities(7)	~ $1.75 billion	n/p

(1) Exelixis' 2025 net product revenues guidance range includes impact of a U.S. wholesale acquisition cost increase of 2.8% for CABOMETYX effective Jan. 1, 2025.
(2) Includes $30.7 million of non-cash stock-based compensation expense.
(3) Includes $40.0 million of non-cash stock-based compensation expense.
(4) Includes $63.2 million of non-cash stock-based compensation expense.
(5) Includes $60.0 million of non-cash stock-based compensation expense.
(6) Preliminary results not yet available.
(7) Cash and marketable securities are composed of cash, cash equivalents and marketable securities. Fiscal year 2025 guidance not provided (n/p).

The preliminary 2024 financial information presented in this press release has not been audited and is subject to change. The complete Exelixis Fourth Quarter and Fiscal Year 2024 Financial Results are planned for release after market on Tuesday, February 11, 2025.

"Entering 2025, Exelixis stands at an inflection point as we work toward our goal of building a multi-product, multi-franchise oncology business," said Michael M. Morrissey, Ph.D., President & CEO, Exelixis. "Exelixis had a very successful 2024 highlighted by strong commercial and financial performance, the favorable ruling on our cabozantinib patent litigation, accelerating progress with the zanzalintinib pivotal trial program and establishing our zanzalintinib clinical development collaboration with Merck. We're carrying that momentum into the new year as we seek to grow cabozantinib franchise revenues, accelerate and expand our zanzalintinib pivotal development program, and advance our diversified therapeutic pipeline of small molecules and biotherapeutics."

Dr. Morrissey continued: "We expect 2025 to be a year of regulatory, clinical and commercial execution as we work toward a potential regulatory approval and launch for cabozantinib in neuroendocrine tumors and prepare for multiple zanzalintinib and pipeline data readouts throughout the year. As cabozantinib's commercial success drives the business forward in the near-term, we're excited by zanzalintinib's potential to surpass cabozantinib's scope and scale in the coming years and to become an important component of our mid- and long-term revenue growth. We're also optimizing our earlier stage pipeline, rapidly profiling compounds and advancing only those with the highest probability of success into full development. We look forward to providing more detailed updates on our pipeline progress at an R&D Day later this year. Finally, we'll maintain our balanced approach to capital allocation, leveraging our strong balance sheet to execute on business development opportunities within the GU and GI oncology space, while using free cash flows to fund our stock repurchase program and return capital to shareholders."

Corporate Updates

Stock Repurchase Program Update. In August 2024, Exelixis announced that the company's Board of Directors authorized the repurchase of up to $500 million of the company's common stock through the end of 2025, the third stock repurchase program undertaken by Exelixis since March 2023. Under this program, as of the end of fiscal year 2024, Exelixis has repurchased $205.6 million of the company's common stock, at an average price of $33.62 per share.

Anticipated Cabozantinib Milestones

Potential Label Expansion and Commercial Launch into NET. Exelixis is preparing for the potential commercial launch of CABOMETYX for the treatment of patients with previously treated advanced NET following the FDA's acceptance of its sNDA and assignment of a PDUFA target action date of April 3, 2025. In January 2025, the FDA notified Exelixis that its sNDA will no longer be the subject of discussion at an Oncologic Drugs Advisory Committee meeting. The regulatory filing was based on positive results from the phase 3 CABINET pivotal trial sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, and led by the NCI-funded Alliance for Clinical Trials in

Oncology. CABINET met its primary endpoint, demonstrating statistically significant and clinically meaningful improvements in progression-free survival (PFS) for patients treated with cabozantinib as compared to placebo in both its pancreatic NET (pNET) and extra-pancreatic NET (epNET) cohorts. Final results from the trial were subsequently presented at the 2024 European Society for Medical Oncology (ESMO) Congress and published in *The New England Journal of Medicine*. In January 2025, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for NET were updated to include cabozantinib as category 1 for certain types of NET following specific treatments, and as a category 2A preferred regimen for several other forms of advanced NET, depending on site of origin and grade. A subgroup analysis from CABINET detailing the experience of patients with advanced gastrointestinal (GI) NET will also be presented at the American Society of Clinical Oncology GI Cancers Symposium (ASCO GI 2025) later this month. Exelixis' partner Ipsen anticipates a decision from the European Medicines Agency on its Marketing Authorization Application for its own proposed NET label expansion in the EU for cabozantinib in 2025. While Exelixis prioritizes supporting the FDA's ongoing review of its proposed NET indication, the company will continue to evaluate the timing of its potential regulatory filing for cabozantinib in metastatic castration-resistant prostate cancer based on the phase 3 CONTACT-02 pivotal study.

Anticipated Development Milestones

Expansion and Acceleration of the Zanzalintinib Pivotal Trial Program. Zanzalintinib is a third-generation tyrosine kinase inhibitor (TKI) that Exelixis believes can become the vascular endothelial growth factor receptor TKI of choice as the solid tumor therapeutic landscapes continue to evolve. The zanzalintinib pivotal development program currently consists of six ongoing or planned pivotal trials, with additional studies to be announced in 2025 and beyond:

- STELLAR-303 is evaluating zanzalintinib in combination with atezolizumab compared with regorafenib in patients with metastatic, refractory non-microsatellite instability-high or non-mismatch repair-deficient colorectal cancer (CRC). The primary endpoint in the study is overall survival (OS) in the patients without liver metastases (NLM). If OS is positive in the NLM population, the study will evaluate OS in the intent-to-treat population that includes patients with and without liver metastases. The study completed enrollment in the third quarter of 2024, and preliminary results are expected in the second half of 2025, dependent on study event rates.
- STELLAR-304 is evaluating zanzalintinib in combination with nivolumab versus sunitinib in previously untreated patients with advanced non-clear cell renal cell carcinoma. The primary endpoints in the trial are PFS and objective response rate. Based on current enrollment status in the trial, the primary endpoint of PFS is expected to be available in the second half of 2025, dependent on study event rates.
- STELLAR-305 is evaluating zanzalintinib in combination with pembrolizumab versus pembrolizumab alone in patients with previously untreated PD-L1-positive recurrent or metastatic squamous cell carcinoma of the head and neck. The study was designed to enroll approximately 250 eligible patients in the phase 2 portion of the trial to be randomly assigned to zanzalintinib in combination with pembrolizumab or pembrolizumab alone to evaluate the activity of the combination therapy. Data from the phase 2 portion are expected be available in the second half of 2025, which would inform whether the data support expansion into the phase 3 portion of the trial, during which an additional 350 patients would be randomized for a total of 600 patients. The primary endpoints in the study are PFS and OS.
- Exelixis also expects to initiate STELLAR-311, a phase 3 pivotal trial evaluating zanzalintinib compared with everolimus as a first oral therapy in patients with advanced NET, regardless of site of origin, in the first half of 2025.
- Additionally, as part of Exelixis' clinical development collaboration with Merck, two pivotal renal cell carcinoma (RCC) studies are planned for 2025. The companies will provide further details on these trials closer to their initiation.

Earlier Stage Zanzalintinib Data Readouts Expected This Year. Exelixis anticipates initial clinical data readouts from zanzalintinib's phase 1b/2 STELLAR-001 and STELLAR-002 clinical studies in the first half of 2025, including data from CRC and RCC cohorts. STELLAR-001 and -002 are evaluating zanzalintinib as a monotherapy and in potentially best-in-class combination regimens across various tumor types. In the nearest term, at ASCO GI 2025 later this month, investigators will present preliminary results from a randomized expansion cohort of STELLAR-001 designed to assess the contribution of atezolizumab to zanzalintinib in patients with previously treated metastatic CRC.

Advance XL309 Phase 1 Program in PARP Inhibitor Refractory Setting and Beyond. XL309, Exelixis' potentially best-in-class small molecule inhibitor of USP1, is currently being evaluated in a phase 1 study as a single agent and in combination with olaparib, a PARP1/2 inhibitor, in patients with advanced solid tumors. Enrollment in the dose escalation cohorts for XL309 monotherapy and olaparib combination are ongoing. The mechanism of action of XL309 and its potential to combine with PARP-inhibitors (PARPi) provide optionality for a robust development program in a variety of solid tumors. Exelixis' clinical development plans for XL309 include its development as a potential therapy for tumors that have become refractory to PARPi therapy, including forms of ovarian, breast and prostate cancers, pursuing potential PARPi combinations, and moving beyond the PARPi market into new areas. Exelixis plans to present data from the XL309 program at a scientific meeting in 2025.

Progress of Phase 1 Clinical Trials for XB010 and XL495. Exelixis initiated clinical development of its XB010 and XL495 pipeline programs in 2024. The company plans to rapidly profile each compound to determine if early clinical data support further advancement toward full development. XB010 is an antibody-drug conjugate (ADC) consisting of a monomethyl auristatin E payload conjugated to a monoclonal antibody targeting the tumor antigen 5T4 and is the first custom ADC generated through Exelixis' biotherapeutics collaboration network. The first-in-human, global phase 1 trial of XB010 is evaluating the compound in patients with locally advanced or metastatic solid tumors. The dose-escalation stage of the study is evaluating XB010 as a single agent and in combination with pembrolizumab to inform the cohort-expansion stage. The expansion cohorts are designed to further assess the tolerability and activity of monotherapy and of the combination in specific indications. XL495 is a novel, potent, small molecule inhibitor of PKMYT1. The first-in-human phase 1 clinical trial of XL495 is evaluating the compound in patients with advanced solid tumors; the dose-escalation stage of the study is designed to determine the maximum tolerated dose of XL495. The expansion cohorts are designed to further assess the tolerability and activity of XL495 both as monotherapy and in combination with select cytotoxic agents in tumor-specific indications. Exelixis plans to present preclinical data from the XL495 program at a scientific meeting in 2025.

Anticipated Discovery Milestones

Three Potential Investigational New Drug (IND) Applications in 2025. Exelixis anticipates advancing three biotherapeutics programs into clinical development this year, including the XB628 PD-L1-NKG2A bispecific antibody, XB064 ILT-2 monoclonal antibody and XB371 TF-topoisomerase I inhibitor ADC. The company expects to file the IND applications for these compounds in 2025 if preclinical data continue to be supportive. Exelixis plans to present preclinical data from one or more of these programs at a scientific meeting in 2025.

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 2024 financial results, 2025 financial guidance and key priorities and milestones for 2025 during the company's presentation at the 43 rd Annual J.P. Morgan Healthcare Conference beginning at 5:15 p.m. PT / 8:15 p.m. ET on Monday, January 13, 2025.

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' anticipation that 2025 will be a year of clinical and regulatory execution and continued growth for its cabozantinib franchise as well as multiple data readouts for zanzalintinib and across its diversified pipeline of small molecules and biotherapeutics with the potential to improve standards of care for patients with cancer; the regulatory review process with respect to Exelixis' sNDA for cabozantinib in previously treated advanced pNET and advanced epNET, including the Prescription Drug User Fee Act target action date assigned by the FDA; Exelixis' 2025 financial guidance; Exelixis' goal of building a multi-product, multi-franchise oncology business and to grow cabozantinib franchise revenues, accelerate and expand its zanzalintinib pivotal development program, and advance its diversified therapeutic pipeline of small molecules and biotherapeutics; Exelixis' expectation for 2025 to be a year of regulatory, clinical and commercial execution including a potential regulatory approval and launch for cabozantinib in neuroendocrine tumors and multiple zanzalintinib and pipeline data readouts; Exelixis' belief in zanzalintinib's potential to surpass cabozantinib's scope and scale in the coming years and to become an important component of the company's mid- and long-term revenue growth; Exelixis' plans to execute on business development opportunities or a stock repurchase program; Exelixis' anticipated cabozantinib milestones, including potential label expansion and commercial launch into NET, the presentation of data from CABINET at ASCO GI 2025, and the potential regulatory path forward for cabozantinib in mCRPC; Exelixis' upcoming development milestones, including expansion and acceleration of the zanzalintinib pivotal trial program and Exelixis' belief that zanzalintinib can become the vascular endothelial growth factor receptor TKI of choice as solid tumor therapeutic landscapes continue to evolve; Exelixis' expectation for initial clinical data readouts from STELLAR-001 and STELLAR-002 in 2025 and the presentation of data from STELLAR-001 at ASCO GI 2025; clinical progress and priorities for XL309, the presentation of XL309 data at a scientific meeting in 2025 and Exelixis' belief that XL309 is a potentially best-in-class small molecule inhibitor of USP1; clinical progress of phase 1 clinical trials for XB010 and XL495; Exelixis' anticipated discovery milestones, including the advancement into clinical development of the XB628 PD-L1-NKG2A bispecific antibody, XB064 ILT-2 monoclonal antibody and XB371 TF-topoisomerase I inhibitor ADC and potential IND filings for these compounds if preclinical data continue to be supportive, and the presentation of preclinical data from one of more of these programs at a scientific meeting in 2025; 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; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere, including the risk that the FDA may not approve cabozantinib as a treatment for pNET or epNET in a timely fashion, if at all; 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, zanzalintinib 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 January 3, 2025. Exelixis is currently in the process of finalizing its financial results for the quarter and fiscal year ended January 3, 2025, and the preliminary financial results presented in this press release are based only upon preliminary information available to Exelixis as of January 12, 2025. 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 January 3, 2025.

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Source: Exelixis, Inc.