



Exelixis Announces Preliminary Fourth Quarter and Full Year 2022 Financial Results, Provides 2023 Financial Guidance, and Outlines Key Priorities and Milestones for 2023

January 8, 2023

- Cabozantinib franchise achieves approximately \$1.4 billion in preliminary U.S. net product revenues for full year 2022, including approximately \$375 million for fourth quarter 2022 –
- Full year 2023 net product revenues guidance of \$1,575 million - \$1,675 million –
- Corporate priorities for 2023 include readout of Phase 3 trials for cabozantinib, expansion of the Phase 3 program for zanzalitinib, progression of XB002 into full development, and advancement of Exelixis' earlier stage pipeline –
- Presentation and webcast at 2023 J.P. Morgan Healthcare Conference on Monday, January 9th at 8:15 p.m. ET / 5:15 p.m. PT –

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 8, 2023-- Exelixis, Inc. (Nasdaq: EXEL) today announced its preliminary unaudited financial results for the fourth quarter and full year 2022, provided financial guidance for full year 2023, and delivered an update on its business. Exelixis expects 2023 to be a year of significant growth and execution as it continues to expand and develop its pipeline of promising biotherapeutics and small molecules and pursues potential near-term label-expansion opportunities for CABOMETYX[®] (cabozantinib).

Preliminary Fourth Quarter and Full Year 2022 Financial Results & 2023 Financial Guidance

Exelixis is providing the following preliminary unaudited 2022 financial results and financial guidance for 2023:

	Fourth Quarter 2022	Full Year 2022	Full Year 2023 Guidance
Total revenues	~ \$415 million	~ \$1,600 million	\$1,775 million - \$1,875 million
Net product revenues	~ \$375 million	~ \$1,400 million	\$1,575 million - \$1,675 million
Cost of goods sold	~ 4.1%	~ 4.1%	4.0% - 5.0%
Research and development expenses	~ \$340 million ⁽¹⁾	~ \$895 million ⁽²⁾	\$1,000 million - \$1,050 million ⁽³⁾
Selling, general and administrative expenses	~ \$120 million ⁽⁴⁾	~ \$460 million ⁽⁵⁾	\$475 million - \$525 million ⁽⁶⁾
Effective tax rate	n/a ⁽⁷⁾	n/a ⁽⁷⁾	20% - 22%

(1) Includes \$10 million of non-cash stock-based compensation expense.

(2) Includes \$45 million of non-cash stock-based compensation expense.

(3) Includes \$45 million of non-cash stock-based compensation expense.

(4) Includes \$15 million of non-cash stock-based compensation expense.

(5) Includes \$62 million of non-cash stock-based compensation expense.

(6) Includes \$55 million of non-cash stock-based compensation expense.

(7) Preliminary results not yet available.

The preliminary 2022 financial information presented in this press release has not been audited and is subject to change. The complete Exelixis Fourth Quarter and Full Year 2022 Financial Results are planned for release after market on Tuesday, February 7, 2023.

"In 2023, Exelixis is advancing our diverse, high-impact pipeline of small molecule and biologic agents for oncology fueled by the continued growth of the cabozantinib commercial franchise," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "We expect to report data from two pivotal trials of cabozantinib, initiate the next wave of phase 3 studies of zanzalitinib (XL092), advance XB002 into full development and add new agents to our portfolio from internal discovery and collaborative efforts. Importantly, we'll continue to pursue additional in-licensing and strategic opportunities to enhance the breadth and depth of our pipeline so that we can make an even greater impact on our mission to help cancer patients recover stronger and live longer."

Anticipated Pipeline Milestones

Exelixis made significant progress in establishing the potential of and adding new assets to the company's pipeline in 2022. In 2022, Exelixis presented data sets for: zanzalitinib (XL092), its next-generation oral tyrosine kinase inhibitor; XB002, its most advanced antibody-drug conjugate (ADC); and XL102, a selective and irreversible cyclin-dependent kinase 7 (CDK7) inhibitor. Three promising biotherapeutics, XB010, XB014 and XB628, from

internal discovery efforts are currently being evaluated in preclinical development, and collaborations were initiated with Cybrexa Therapeutics (Cybrexa) and Sairopa B.V. (Sairopa) to advance the CBX-12 and ADU-1805 programs, respectively, which were the subject of exclusive clinical option and license agreements signed in the fourth quarter of 2022.

Expansion of pivotal trial program for zanzalintinib: In 2023, Exelixis plans to expand the phase 3 development program for zanzalintinib (XL092) with multiple new phase 3 pivotal trial initiations of zanzalintinib in combination with several immuno-oncology (IO) therapies. In 2022, Exelixis initiated STELLAR-303, which evaluates zanzalintinib in combination with atezolizumab versus regorafenib in patients with colorectal cancer (CRC) that is not microsatellite instability-high or mismatch repair-deficient, who have progressed after or are intolerant to the current standard of care, as well as STELLAR-304, which evaluates zanzalintinib in combination with nivolumab versus sunitinib in patients with advanced non-clear cell renal cell carcinoma. As previously stated, Exelixis intends to develop zanzalintinib in novel combination regimens in a broad array of future potential indications, including those where cabozantinib has demonstrated anti-tumor activity.

Advancement of the XB002 JEWEL development program: In 2023, Exelixis intends to accelerate the development of XB002, its next-generation tissue factor-targeting ADC, both as a monotherapy and in combination with IO and other targeted therapies, across a wide range of tumor types. The dose-escalation stage of JEWEL-101, the first-in-human phase 1 study evaluating XB002 as a single agent and in combination with nivolumab, is ongoing and the company expects to initiate the cohort expansion stage of the study after the recommended dose and/or the maximum-tolerated dose for XB002 have been determined, as well as advance additional combination cohorts in the study to identify sensitive tumor types. Anticipated tumor cohorts across the trial include forms of non-small cell lung, ovarian, cervical, urothelial, squamous cell head and neck, pancreatic, esophageal, prostate, and breast. In October 2022, Exelixis presented [promising initial results](#) from the ongoing dose-escalation stage of JEWEL-101, demonstrating that XB002 was well-tolerated across multiple dose levels with a pharmacokinetic analysis supporting the ability of XB002 to remain stable after infusion with low levels of free payload in circulation. The company expects to move into full development by year-end.

Advancement of the XL102 QUARTZ development program: In 2023, Exelixis intends to advance the first-in-human QUARTZ-101 phase 1 trial evaluating XL102, its potent, selective, irreversible and orally bioavailable small molecule CDK7 inhibitor into the cohort expansion and potential combination cohorts. The phase 1 QUARTZ-101 study is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity and effect on biomarkers of XL102 administered alone and in multiple combination regimens in patients with advanced solid tumors. In December 2022, Exelixis presented [initial dose-escalation results](#) from the QUARTZ-101 study, demonstrating that XL102 was well-tolerated at evaluated dose levels with a pharmacokinetic analysis showing rapid absorption of XL102 and an elimination half-life of 5-9 hours. Exelixis expects to evaluate the anti-tumor activity and efficacy of XL102 in additional patients in the single-agent dose-escalation cohorts, in the tumor-specific cohort-expansion stage and in planned combination cohorts. In the cohort-expansion stage of QUARTZ-101, XL102 will be evaluated in patients with certain types of ovarian, breast and prostate cancers.

Advancement of CBX-12 clinical program in collaboration with Cybrexa: Exelixis expects its partner Cybrexa to continue to advance its phase 1 clinical study program for CBX-12 throughout 2023, including dose-expansion cohorts. CBX-12 is a clinical-stage, first-in-class peptide-drug conjugate that utilizes Cybrexa's proprietary alphalex™ technology to enhance delivery of exatecan to tumor cells. It is designed to increase the therapeutic index of topoisomerase I inhibition by delivering exatecan, a highly potent, second-generation topoisomerase I inhibitor, directly to the tumor cells using a target independent approach activated by the acidic microenvironment of solid tumors. Under the terms of the agreement announced in November 2022, Exelixis has the option to acquire CBX-12 upon evaluation of a pre-specified clinical data package that includes certain phase 1 results.

Planned Investigational New Drug (IND) filing for ADU-1805 program, in collaboration with Sairopa: In the first quarter of 2023, Exelixis expects its partner Sairopa to file an IND for ADU-1805, a potential best-in-class monoclonal antibody targeting SIRPα to block the SIRPα-CD47 checkpoint. 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, and has been optimized to bind preferentially to SIRPα vs. 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-SIRPα antibodies upon review of data from prespecified phase 1 clinical studies of ADU-1805 to be completed by Sairopa during the option period.

Advancement of Development Candidates (DCs) XB010 and XB014 toward IND filing: In 2023, Exelixis plans to advance XB010, the first custom ADC generated through the company's biotherapeutics network of collaborations, and XB014, the company's first bispecific antibody designated as a DC in August 2022, through preclinical development and IND-enabling studies, toward potential IND filings in early 2024. XB010 targets the oncofetal antigen 5T4, which is overexpressed on a broad array of solid tumors including non-small cell lung cancer, head and neck squamous cell carcinomas, and gastric and breast carcinomas, and utilizes the SMARTag® site specific conjugation platform from Catalent, Inc. to produce a homogeneous ADC with a defined drug-antibody ratio coupled to a high affinity antibody Exelixis sourced from Invenra, Inc. (Invenra). XB014 consists of a bispecific antibody, with a PDL1 targeting arm along with a CD47 targeting arm to block a macrophage checkpoint, also developed through Exelixis' collaboration with Invenra.

DC designation for XB628: Today, Exelixis announced it has designated XB628 as its latest DC and plans to advance the program through preclinical development in 2023, toward a potential IND filing in 2024. Comprising a PDL1 targeting arm and an NKG2A targeting arm, XB628 is the company's second bispecific antibody program developed through its collaboration with Invenra.

Discovery Expansion and Anticipated Milestones

In 2022, Exelixis enhanced the capacity and capabilities of its small molecule discovery efforts and utilized its broad collaboration network to build a differentiated biotherapeutics platform focused on the identification and optimization of next-generation ADCs, bispecific antibodies and other biologics with promising preclinical activity. In 2023, Exelixis is advancing more than 10 discovery programs through internal and collaborative efforts and expects to progress up to five new development candidates into preclinical development, encompassing multiple modalities and mechanisms across small molecules and biotherapeutics.

Anticipated Cabozantinib Milestones

"In the ten years since its initial FDA approval, cabozantinib has evolved from an orphan indication to a global oncology franchise that benefits tens of thousands of patients annually," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "In 2022, cabozantinib generated approximately \$1.4 billion in preliminary U.S. net product revenues, further reinforcing its status as a leading therapy for forms of renal, liver, and thyroid cancer. We're committed to maximizing cabozantinib's clinical and commercial potential – including through the ongoing CONTACT clinical trials, which

represent the final Exelixis-sponsored pivotal trials of the compound – as our pipeline buildout proceeds.”

Pivotal trial progress and data readouts anticipated in 2023: During the first half of the year, Exelixis expects to report top-line results for the progression-free survival endpoint from CONTACT-03, the phase 3 pivotal trial sponsored by Roche evaluating the combination of cabozantinib and atezolizumab versus cabozantinib monotherapy in a form of renal cell carcinoma (RCC) in patients who progressed during or following treatment with an immune checkpoint inhibitor as the immediate preceding line of therapy. In the second half of the year, the company anticipates completion of enrollment and expects to report top-line results for the progression-free survival endpoint for CONTACT-02, the phase 3 pivotal trial sponsored by Exelixis evaluating the combination of cabozantinib and atezolizumab in patients with metastatic castration-resistant prostate cancer who have been previously treated with one novel hormonal therapy. Also expected in 2023 is the next overall survival analysis from COSMIC-313, the phase 3 pivotal trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC.

Cabozantinib Abbreviated New Drug Application (ANDA) Litigation: The United States District Court for the District of Delaware has scheduled a second bench trial for Exelixis’ ongoing ANDA lawsuit against MSN Pharmaceuticals, Inc. for October 2023. Exelixis is confident in its cabozantinib patent estate and will vigorously defend the patents at issue.

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 fourth quarter and full year 2022 financial results, 2023 financial guidance, and key priorities and milestones for 2023 during the company’s presentation at the J.P. Morgan Healthcare Conference beginning at 8:15 p.m. ET / 5:15 p.m. PT on Monday, January 9, 2022.

To access the webcast link, log onto www.exelixis.com and proceed to the News & Events / Event Calendar page under the Investors & Media heading. Please connect to the company’s website at least 15 minutes prior to the presentation to ensure adequate time for any software download that may be required to listen to the webcast. 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 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, 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 Twitter, like [Exelixis, Inc.](https://www.facebook.com/Exelixis) on Facebook and follow [Exelixis](https://www.linkedin.com/company/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 2023 will be a year of significant growth and execution as it continues to expand and develop its pipeline of promising biotherapeutics and small molecules and pursues potential near-term label-expansion opportunities for CABOMETYX; Exelixis’ 2023 financial guidance; Exelixis’ expectations in 2023 to report data from two pivotal trials of cabozantinib, initiate the next wave of phase 3 studies of zanzalintinib, advance XB002 into full development and add new agents to its portfolio from internal discovery and collaborative efforts; Exelixis’ plans to continue to pursue additional in-licensing and strategic opportunities to enhance the breadth and depth of its pipeline and make an even greater impact on its mission to help cancer patients recover stronger and live longer; Exelixis’ plans to expand the phase 3 development program for zanzalintinib in 2023 with multiple new phase 3 pivotal trial initiations evaluating zanzalintinib in novel combination regimens with several IO therapies across a broad array of future potential indications, including those where cabozantinib has demonstrated anti-tumor activity; Exelixis’ plans in 2023 to accelerate the development of XB002, both as a monotherapy and in combination with IO and other targeted therapies, across a wide range of tumor types, and Exelixis’ expectation that XB002 will move into full development by year-end; Exelixis’ expectation it will initiate the cohort expansion stage of the JEWEL-101 study after the recommended dose and/or the maximum-tolerated dose for XB002 have been determined, as well as advance additional combination cohorts, with anticipated cohorts across the trial to include forms of non-small cell lung, cervical, urothelial, squamous cell head and neck, pancreatic, esophageal, prostate and breast cancers; Exelixis’ plans in 2023 to continue evaluating the anti-tumor activity and efficacy of XL102 in the QUARTZ-101 study, with additional patients in the single-agent dose-escalation cohorts, and to advance the study into the tumor-specific cohort expansion stage, including in patients with certain types of ovarian, breast and prostate cancers, as well as in potential combination cohorts; Exelixis’ expectation that its partner Cybrexa will continue to advance its phase 1 clinical study program for CBX-12 throughout 2023, including dose-expansion cohorts; Exelixis’ expectation that its partner Sairopa will file an IND for ADU-1805 in the first quarter of 2023; the potential for ADU-1805 to be a best-in-class monoclonal antibody targeting SIRPα to block the SIRPα-CD47 checkpoint, which has the potential to improve the immune system’s ability to attack tumors, and Exelixis’ belief that ADU-1805 may address a broader patient population than other SIRPα-directed therapies; Exelixis’ plans in 2023 to advance XB010 and XB014 through preclinical development and IND-enabling studies toward potential IND filings in early 2024; Exelixis’ plans in 2023 to advance XB628 through preclinical development toward a potential IND filing in 2024; Exelixis’ anticipated discovery expansion activities and milestones in 2023, including plans to advance more than 10 discovery programs through internal and collaborative efforts and expectation to progress up to five new development candidates into preclinical development, encompassing multiple modalities and mechanisms across small molecules and biotherapeutics; Exelixis’ commitment to maximizing cabozantinib’s clinical and commercial potential – including through the ongoing CONTACT clinical trials, which represent the final pivotal trials of the compound – as the pipeline buildout proceeds; Exelixis’ expectation it will report top-line results for the progression-free survival endpoint from CONTACT-03 during the first half of 2023, and to complete enrollment in CONTACT-02 and report top-line results for the progression-free survival endpoint from CONTACT-02 during the second half of 2023, as well as report results from the next overall survival analysis from COSMIC-313 during 2023; Exelixis’ confidence in its cabozantinib patent estate and plans to vigorously defend the patents at issue in a second bench trial for its ongoing lawsuit against MSN Pharmaceuticals, scheduled for October 2023; 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 products; 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, including as a result of the COVID-19 pandemic and other global events; and other factors discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q submitted to the Securities and Exchange Commission (SEC) on November 1, 2022, 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.

In addition, this press release includes Exelixis' preliminary financial results for the quarter and fiscal year ended December 30, 2022. Exelixis is currently in the process of finalizing its full financial results for the quarter and fiscal year ended December 30, 2022, and the preliminary financial results presented in this press release are based only upon preliminary information available to Exelixis as of January 8, 2023. Exelixis' preliminary financial results should not be viewed as a substitute for full 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 30, 2022.

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