Exelixis Announces Preliminary Fourth Quarter and Full Year 2021 Financial Results, Provides 2022 Financial Guidance, and Outlines Key Priorities and Milestones for 2022

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— Corporate priorities for 2022 include initial readout of up to three cabozantinib pivotal trials; initiation of pivotal trial program for XL092; expansion of clinical programs for XL092, XB002 and XL102; and multiple new development candidates from small molecule and biologics programs —

— Cabozantinib franchise achieves significant milestone with approximately $1.08 billion in preliminary U.S. net product revenues for full year 2021, including approximately $300 million for fourth quarter 2021 —

— Full year 2022 net product revenues guidance of $1.325 billion to $1.425 billion —

— Presentation and webcast at 2022 J.P. Morgan Healthcare Conference on Monday, January 10th at 5:15 p.m. ET / 2:15 p.m. PT —

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 9, 2022-- Exelixis, Inc. (Nasdaq: EXEL) today announced its preliminary unaudited financial results for the fourth quarter and full year 2021, provided financial guidance for full year 2022, and delivered an update on its business. Exelixis expects 2022 to be a year of financial, pipeline and corporate growth as it rapidly builds out its portfolio of promising small molecules and biologics, maximizes near-term opportunities for CABOMETYX through four ongoing phase 3 pivotal trials, and scales its discovery and development team, including the company's recently announced expansion to the East Coast.

Preliminary Fourth Quarter and Full Year 2021 Financial Results & 2022 Financial Guidance

Exelixis is providing the following preliminary unaudited 2021 financial results and financial guidance for 2022:

	Fourth Quarter 2021	Full Year 2021	Full Year 2022 Guidance
Net product revenues	~ $300 million	~ $1.08 billion	$1.325 billion - $1.425 billion
Cost of goods sold	~ 4.3%	~ 4.9%	5% - 6% of net product revenues
Research and development expenses	~ $220 million(1)	~ $690 million(2)	$725 million - $775 million(3)
Selling, general and administrative expenses	~ $100 million(4)	~ $400 million(5)	$400 million - $450 million(6)
Effective tax rate	n/a(7)	n/a(7)	20% - 22%

The table above does not include Fourth Quarter or Full Year 2021 Total Revenues preliminary results or Full Year 2022 Total Revenues guidance as Exelixis is waiting for its partners to provide final confirmation of their 2021 cabozantinib net sales performance. Exelixis will provide these metrics when the company reports its fourth quarter and full year 2021 financial results on February 17, 2022.

(1) Includes $8 million of non-cash stock-based compensation expense.
(2) Includes $46 million of non-cash stock-based compensation expense.
(3) Includes $45 million of non-cash stock-based compensation expense.
(4) Includes $14 million of non-cash stock-based compensation expense.
(5) Includes $73 million of non-cash stock-based compensation expense.
(6) Includes $50 million of non-cash stock-based compensation expense.
(7) Preliminary results not yet available.

The preliminary 2021 financial information presented in this press release has not been audited and is subject to change. The complete Exelixis Fourth Quarter and Full Year 2021 Financial Results are planned for release after market on Thursday, February 17, 2022.

"As we enter 2022, Exelixis is on a clear path to becoming a multi-product oncology company. Fueled by the commercial success of CABOMETYX, we are rapidly advancing our expanding portfolio of differentiated therapeutic candidates with the potential to improve outcomes for a growing number of patients with cancer," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer, Exelixis. "We expect to have multiple, significant growth catalysts in 2022, including the potential for top-line readouts from up to three CABOMETYX phase 3 pivotal trials, the initiation of a robust pivotal trial program for XL092, and the expansion of our clinical programs for XB002 and XL102. Our preclinical pipeline continues to advance with multiple new development candidates expected in 2022 from both small molecule and biotherapeutics platforms, opening the door to substantial long-term growth opportunities in new indications and modes of therapy."

Dr. Morrissey continued: "In addition to advancing our current clinical and preclinical pipelines, our business development team continues to evaluate new platform technologies and compounds to bring into our development organization, now led by Dr. Vicki L. Goodman, our Executive Vice President, Product Development & Medical Affairs and Chief Medical Officer. As 2022 begins, we remain a committed and rapidly growing team with global aspirations, with more focus and drive than ever in our mission to help cancer patients recover stronger and live longer."

Anticipated Cabozantinib Milestones

"In 2021, cabozantinib generated approximately $1.08 billion in preliminary U.S. net product revenues, a major milestone that reflects its position as a leading treatment for advanced renal cell carcinoma and growing opportunities in forms of thyroid and liver cancer," noted Dr. Morrissey. "The success of the cabozantinib franchise to date is an essential driver of our current growth trajectory, supporting the buildouts of our new corporate headquarters building in Alameda, new 'Exelixis East' facilities in the greater Philadelphia area and ultimately, the expansion of our operations and footprint

internationally. Over the course of this year and into 2023, we're excited about the potential for data from the COSMIC-313 and CONTACT clinical trials to broaden cabozantinib's impact on difficult-to-treat cancers and generate additional product revenues to support our continued pipeline innovation and growth."

Multiple pivotal clinical trial readouts anticipated in 2022: During the first half of the year, top-line results from COSMIC-313, the phase 3 pivotal trial evaluating the triplet combination of cabozantinib, nivolumab (OPDIVO®) and ipilimumab (YERVOY®) versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk renal cell carcinoma (RCC); in early 2022, final overall survival data from COSMIC-312, the phase 3 pivotal trial evaluating the combination of cabozantinib and atezolizumab in previously untreated hepatocellular carcinoma; and initial data in the second half of 2022 from CONTACT-01 and CONTACT-03, the phase 3 pivotal trials that are evaluating cabozantinib in combination with atezolizumab in forms of non-small cell lung cancer (NSCLC) and RCC, respectively.

Cabozantinib Abbreviated New Drug Application (ANDA) Litigation: The United States District Court for the District of Delaware has scheduled a bench trial for Exelixis' ANDA lawsuit against MSN Pharmaceuticals, Inc. for May 2022. Exelixis is confident in its patents relating to cabozantinib and will vigorously defend the patents at issue in this lawsuit as well as its broader cabozantinib intellectual property estate.

Anticipated Pipeline Milestones

"Exelixis has a diverse and exciting portfolio of emerging clinically differentiated compounds — one that we expect will continue to grow as we build for the future and bring additional programs into clinical development," said Vicki L. Goodman, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. "In 2022, we'll take XL092, our next-generation, oral tyrosine kinase inhibitor, into pivotal trials and significantly expand the clinical programs for XL092, XB002 and XL102."

Launch of pivotal trial program for XL092: Exelixis expects to initiate the first global phase 3 pivotal trial for XL092 in the first half of 2022, with others to follow throughout the year. The first trial, STELLAR-303, will evaluate XL092 in combination with atezolizumab versus regorafenib in patients with metastatic microsatellite stable colorectal cancer (CRC) who have progressed after or are intolerant to the current standard of care. Preclinical data and emerging results from multiple phase 1b clinical trials of XL092, alone and in combination with immune-oncology (IO) therapies, reinforce Exelixis' belief in the opportunity for XL092, which pairs a target profile similar to cabozantinib with a potentially significantly improved safety profile. The decision to initiate STELLAR-303 is also supported by data from a CRC cohort of COSMIC-021, the ongoing phase 1b trial of cabozantinib in combination with atezolizumab and the CAMILLA investigator-sponsored trial of cabozantinib in combination with durvalumab plus or minus tremelimumab. Results from both of these trials have been accepted for presentation at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium, which is being held January 20-22, 2022. As previously stated, Exelixis intends to develop XL092 in novel combination regimens in a broad array of future potential indications where cabozantinib has demonstrated RECIST v1.1 anti-tumor activity.

Expansion of the XL092 STELLAR-001/-002 clinical program: Exelixis expects to expand the ongoing phase 1b STELLAR-001 and STELLAR-002 studies, which are evaluating XL092 in combination with several IO therapies, into potential new tumor types, and IO and other targeted therapy combination regimens throughout 2022. Clinical updates from these trials are expected in 2022.

Acceleration of the XB002 clinical program: The single-agent dose escalation cohort for the ongoing phase 1 trial of XB002 continues enrolling, and the study is expected to move into its cohort expansion and combination phase shortly. Anticipated cohorts across the trial include forms of NSCLC, ovarian, cervical, urothelial, squamous cell head and neck, pancreatic, esophageal, metastatic castrate resistant prostate, triple negative and hormone receptor-positive breast cancer. Based on early clinical data supportive of a potentially differentiated and best-in-class profile, Exelixis intends to aggressively expand development of XB002, both as a monotherapy and in combination with immune checkpoint inhibitors and other targeted therapies, across a wide range of tumor types, including indications other than those currently addressed by commercially available tissue factor (TF)-targeted therapies. Last week, the company also announced an amendment to its agreement with Iconic Therapeutics, Inc., which initially discovered XB002, that creates the foundation for a potential TF-targeting oncology franchise from Exelixis. Exelixis expects to provide clinical updates and present data from the ongoing phase 1 study of XB002 in 2022.

Expansion of the XL102 clinical program: The ongoing phase 1 study of XL102, a potent, selective and orally bioavailable small molecule cyclin dependent kinase 7 (CDK7) inhibitor, is currently in its dose escalation phase, with enrollment ongoing in the single-agent and combination therapy cohorts. Building on the preclinical activity profile, as well as pharmacodynamic data from the early clinical experience as a monotherapy, Exelixis expects to initiate the cohort expansion phase of the study with combination regimens in hormone receptor-positive breast cancer and other tumor types in the first half of the year. Exelixis expects to provide clinical updates and present initial data from the ongoing phase 1 study of XL102 in 2022.

Initiation of phase 1 trial for XL114: Exelixis expects to initiate dosing in the phase 1 trial of XL114 in patients with non-Hodgkin's lymphoma during the first half of 2022. In October 2021, the FDA accepted the Investigational New Drug Application for XL114, which inhibits the CARD11-BCL10-MALT1 signaling pathway that promotes lymphocyte survival and proliferation.

Exelixis planned expansion to the East Coast: Exelixis announced plans to expand its development operations to the East Coast with the recent hire of Dr. Goodman. This expansion will complement the company's strong and growing West Coast development team and enable the company to move even faster on behalf of patients, including by laying additional groundwork for potential future growth outside the United States. In parallel, Exelixis will continue to maintain and expand its global headquarters and oncology drug development activities in Alameda. Exelixis will share more information on its East Coast plans as they evolve over the course of this year.

Discovery Expansion and Anticipated Milestones

In 2021, Exelixis opened a new laboratory building on its campus, effectively tripling its available lab space and significantly enhancing the capacity and capabilities of its small molecule discovery efforts. At the same time, the company made substantial progress on its biologics discovery activities, including through its ADC platform focused on the identification and optimization of ADCs with excellent activity *in vitro* and *in vivo*.

"We continue to make significant progress across our portfolio of internal discovery projects and suite of collaborations to generate next-generation small molecule therapeutics, antibody-drug conjugates and other biotherapeutics," said Peter Lamb, Ph.D., Executive Vice President, Scientific Strategy and Chief Scientific Officer, Exelixis. "We are increasingly excited about our robust ADC platform that maximizes optionality and enables innovation to optimize potential development candidates and rapidly facilitate the build-out of an ADC pipeline."

Potential new development candidates: In 2022, Exelixis is currently advancing more than ten 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 biologics.

With respect to biotherapeutics, these include XB010, the first custom ADC generated through the company's collaboration network, which was designated a development candidate in late 2021 and will enter preclinical development shortly. In designing XB010, Exelixis sourced antibodies from Invenra, Inc. (Invenra) and worked with affiliates of Catalent, Inc. (Catalent) to design a novel ADC with broad potential. XB010 targets the oncofetal antigen 5T4 which is overexpressed on a broad array of solid tumors including NSCLC, head and neck squamous cell carcinomas, and gastric and breast carcinomas, and utilizes Catalent's SMARTag® site specific conjugation platform to produce a homogeneous ADC with a defined drug-antibody ratio. XB010 also incorporates Catalent's next-generation linker technology, which is designed to be significantly more stable than first-generation approaches.

Additional ADCs advancing through discovery target a range of tumor antigens including AMHR2, ROR1/2, TF and DLL3 and utilize a variety of conjugation technologies and payloads. In addition, Exelixis is advancing two bispecific programs through its Invenra collaboration that combine a PD-L1 targeting arm with either a CD47 targeting arm to block a macrophage checkpoint, or an NKG2A targeting arm to promote NK cell activation in the tumor microenvironment.

Exelixis discovery teams are also advancing multiple small molecule programs internally and through the company's collaborations with Aurigene, Inc. (Aurigene), StemSynergy Therapeutics, Inc. (StemSynergy) and STORM Therapeutics Ltd (STORM). The small molecule portfolio includes novel inhibitors for the G9a (internal), MALT1 and CDK12 (Aurigene), Notch and CK1α activators (StemSynergy) and ADAR1 (STORM). These programs are a mixture of next-generation approaches to established targets (G9a and MALT1) and opportunities to be first-in-class (CDK12, CK1α, Notch and ADAR1). Additional early-stage programs are also in progress in Exelixis' discovery laboratories, as well as through our collaborations with Aurigene and STORM.

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 2021 financial results, 2022 financial guidance, and key priorities and milestones for 2022 during the company's presentation at the J.P. Morgan Healthcare Conference beginning at 5:15 p.m. ET / 2:15 p.m. PT on Monday, January 10, 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 14 days.

About Exelixis

Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model system genetics, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. Our discovery efforts have resulted in four commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing our existing therapeutic assets with targeted business development activities and internal drug discovery — all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Exelixis is a member of the Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. For more information about Exelixis, please visit www.exelixis.com, follow @ExelixisInc on Twitter or like Exelixis, Inc. on Facebook.

Forward-Looking Statements and Preliminary Financial Results

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' expectation that 2022 will be a year of financial, pipeline and corporate growth as it rapidly builds out its portfolio of promising small molecules and biologics, maximizes near-term opportunities for CABOMETYX through four ongoing phase 3 pivotal trials, and scales its discovery and development team, including the company's recently announced expansion to the East Coast; Exelixis' 2022 financial guidance; the potential of Exelixis' portfolio of differentiated therapeutic candidates to improve outcomes for a growing number of patients with cancer as Exelixis continues its path towards becoming a multi-product oncology company; Exelixis' expectation for multiple, significant growth catalysts in 2022, including the potential for top-line readouts from up to three CABOMETYX phase 3 pivotal trials, the initiation of a robust pivotal trial program for XL092, and the significant expansion of the clinical programs for XL092, XB002 and XL102; Exelixis' plans to advance multiple new development candidates in 2022 from both small molecule and biologics platforms, which could lead to substantial long-term growth opportunities in new indications and modes of therapy; the potential for data from COSMIC-313 and CONTACT clinical trials to broaden cabozantinib's impact on difficult-to-treat cancers and generate additional product revenue to support Exelixis' continued pipeline innovation and growth during 2022 and 2023; Exelixis' expectation for top-line results from COSMIC-313 during the first half of 2022, as well as final overall survival data from COSMIC-312 in early 2022 and initial data from CONTACT-01 and CONTACT-03 during the second half of 2022; Exelixis' plans to defend its cabozantinib patents in its lawsuit against MSN Pharmaceuticals at a bench trial scheduled for May 2022; Exelixis' clinical development plans for XL092, including the initiation of the STELLAR-303 phase 3 pivotal trial in patients with CRC during the first half of 2022 and expansion of the ongoing STELLAR-001 and STELLAR-002 phase 1b trials into potential new tumor types and combination regimens throughout 2022, as well as Exelixis' expectation for clinical updates from the STELLAR-001 and STELLAR-002 trials during 2022; Exelixis' belief in the opportunity for XL092, which pairs a target profile similar to cabozantinib with a potentially significantly improved safety profile; Exelixis' clinical development plans for XB002, including the planned initiation of the cohort expansion and combination phase across multiple tumor types, as well as Exelixis' expectation for clinical updates and to present data from the ongoing phase 1 study in 2022; the potentially differentiated and best-in-class profile of XB002 and Exelixis' intention to expand development of XB002, both as a monotherapy and in combination with other therapies, into indications other than those currently addressed by commercially available TF-targeting therapies, as well as Exelixis' belief that the amended collaboration with Iconic Therapeutics, Inc. creates the foundation for a potential TF-targeting oncology franchise; Exelixis' clinical development plans for XL102, including the planned initiation of the cohort expansion phase of the study with combination regimens during the first half of 2022, as well as Exelixis' expectation for clinical updates and to present initial data from the ongoing phase 1 study in 2022; Exelixis' plans to initiate dosing in the phase 1 trial of XL114 in patients with non-Hodgkin's lymphoma during the first half of 2022; Exelixis' plans to expand its development operations to

the East Coast and for potential future growth outside the U.S., as well as to maintain and expand the global headquarters and oncology drug development activities in Alameda, and Exelixis' intention to share more information on its East Coast plans as they evolve over the course of 2022; Exelixis' discovery programs and plans to advance up to five new development candidates into preclinical development during 2022, including XB010 and additional ADC programs, and also small molecule programs that encompass a mixture of both next-generation approaches to established targets and opportunities to be first-in-class treatments; Exelixis' plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery; 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 continuing COVID-19 pandemic and its impact on Exelixis' clinical trial, drug discovery and commercial activities; 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 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; 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 2, 2021, 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 31, 2021. Exelixis is currently in the process of finalizing its full financial results for the quarter and fiscal year ended December 31, 2021, and the preliminary financial results presented in this press release are based only upon preliminary information available to Exelixis as of January 9, 2022. 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 31, 2021.

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