Exelixis Announces Preliminary Fourth Quarter and Full Year 2020 Financial Results, Provides 2021 Financial Guidance, and Outlines Key Priorities and Anticipated Milestones For 2021

January 10, 2021

– Cabozantinib Franchise Preliminary Net Product Revenue of $200 million for the Fourth Quarter 2020, and $741 million for the Full Year 2020 –

– Full Year 2021 Net Product Revenue Guidance of $950 million to $1,050 million –

– Corporate priorities for 2021 include potentially filing supplemental New Drug Applications for cabozantinib in three additional indications –

– Presentation and webcast at 2021 J.P. Morgan Healthcare Conference on Monday, January 11th at 5:20 PM EST / 2:20 PM PST –

ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 10, 2021-- Exelixis, Inc. (Nasdaq: EXEL) today announced its preliminary unaudited financial results for the fourth quarter and full year 2020, provided financial guidance for full year 2021, and delivered an update on its business. This 2021 financial guidance takes into consideration the anticipated U.S. Food and Drug Administration (FDA) approval and commercial launch of CABOMETYX® (cabozantinib) in combination with OPDIVO® (nivolumab) as a first-line treatment for patients with advanced renal cell carcinoma (RCC), which has a Prescription Drug Use Fee Act (PDUFA) target action date of February 20, 2021.

Preliminary Fourth Quarter and Full Year 2020 Financial Results & 2021 Financial Guidance

Exelixis is providing the following preliminary unaudited 2020 financial results and financial guidance for 2021:

	Fourth Quarter 2020	Full Year 2020	Full Year 2021 Guidance
Total revenues	$270 million	$988 million	$1,150 million - $1,250 million
Net product revenues	$200 million	$741 million	$950 million - $1,050 million
Cost of goods sold	4.5%	4.9%	~ 5-6% of net product revenues
Research and development expenses	$155 million(1)	$549 million(2)	$600 million - $650 million(3)
Selling, general and administrative expenses	$83 million(4)	$295 million(5)	$375 million - $425 million(6)
Effective tax rate	n/a(7)	n/a(7)	20% - 22%
Cash and investments at year-end(8)	~ $1.5 billion		$1.6 billion - $1.7 billion

(1) Includes $7.1 million of non-cash stock-based compensation expense.
(2) Includes $37.2 million of non-cash stock-based compensation expense.
(3) Includes $45.0 million of non-cash stock-based compensation expense.
(4) Includes $12.2 million of non-cash stock-based compensation expense.
(5) Includes $67.9 million of non-cash stock-based compensation expense.
(6) Includes $60.0 million of non-cash stock-based compensation expense.
(7) Preliminary results not yet available.
(8) This cash and investments guidance does not include any potential new business development activity.

The preliminary 2020 financial information presented in this press release has not been audited and is subject to change. The complete Exelixis Fourth Quarter and Full Year 2020 Financial Results are planned for release after market on Wednesday, February 10, 2021.

“2020 was a year of focused execution for Exelixis as we strengthened our foundation to potentially accelerate top-line revenue growth in 2021 and beyond. Throughout the year, the team advanced all of the components of our business and navigated the challenging COVID-19 pandemic environment to report data from late-stage trials, start new pivotal studies, ready next-generation Exelixis compounds for the clinic, and bring new assets and technologies into our pipeline,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. “We start 2021 with significant momentum as we prepare for the anticipated FDA approval of CABOMETYX in combination with OPDIVO based on the CheckMate -9ER trial. With the preliminary 2020 financial results announced today along with our 2021 guidance, we believe we are well positioned to deliver significant revenue growth throughout the new year and beyond as we capitalize on CABOMETYX’s future potential indications.”

Dr. Morrissey continued: “In 2021 and beyond, we intend to pursue additional cabozantinib regulatory approvals and clinical development activities that unlock new treatment regimens, benefit a substantially greater number of patients and create the potential for a multi-billion-dollar franchise. CABOMETYX revenue directly supports our emerging pipeline of compounds with the potential to generate significant clinical and commercial value, including XL092, our improved next-generation oral, multi-targeted tyrosine kinase inhibitor that builds on our experience with cabozantinib. We expect to advance XL092 into pivotal trials in 2021 and believe it may ultimately become a source of long-term revenue for Exelixis. Additional programs are advancing alongside XL092, including XL102, our small molecule CDK7 inhibitor; XB002, our first antibody-drug conjugate; and multiple other programs. Overall, between our commercial, clinical, and pipeline activities, we are well on our way to becoming a multi-product oncology company that delivers on our mission to help cancer patients recover stronger and live longer.”

Ahead of the company's presentation at the J.P. Morgan Healthcare Conference tomorrow, Exelixis is also announcing its corporate priorities and anticipated key milestones for 2021, including potential supplemental New Drug Applications (sNDAs) for CABOMETYX, expanded clinical development activities for XL092, and multiple Investigational New Drug applications (INDs) for preclinical assets.

CABOMETYX and OPDIVO Combination for First-line Advanced RCC Represents Large and Growing Commercial Opportunity

- In August 2020, Exelixis announced the submission of an sNDA to the FDA for CABOMETYX in combination with Bristol Myers Squibb's (BMS) OPDIVO for patients with advanced RCC. In October 2020, Exelixis and BMS announced that the FDA had accepted each company's regulatory application, granted Priority Review, and assigned a PDUFA goal date, or target action date, of February 20, 2021. Exelixis is ready to commercially launch this combination regimen in the United States, where an estimated 15,000 patients with advanced RCC are eligible for first-line treatment every year and with immune checkpoint inhibitor (ICI) combination therapy consisting of approximately 80% of that market. Based on the efficacy, safety and longer duration of therapy as observed in the CheckMate -9ER trial, Exelixis estimates that a doubling of CABOMETYX revenues in RCC alone may be achievable, with a potential $1.5 billion annualized run rate exiting 2022.

Potential sNDA Submissions for Cabozantinib in 2021

- **Relapsed radioiodine-refractory differentiated thyroid cancer (DTC):** Exelixis expects to file an sNDA for the approval of cabozantinib monotherapy in patients with radioactive iodine-refractory DTC previously treated with a vascular endothelial growth factor receptor-targeted therapy. The sNDA will be based on the positive results from the phase 3 pivotal COSMIC-311 trial, which met its co-primary endpoint of progression-free survival (PFS) in December 2020.
- **Advanced hepatocellular carcinoma (HCC):** Exelixis expects to report top-line data from COSMIC-312, a global phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab (TECENTRIQ®), F. Hoffmann-La Roche Ltd.'s (Roche) anti-PD-L1 ICI, versus sorafenib in previously untreated advanced HCC, for the co-primary endpoints of PFS and overall survival (OS) in the first half of 2021. If the data are supportive, the company anticipates filing an sNDA in 2021, and its partner Ipsen Pharma SAS would also seek to file marketing applications with regulatory agencies in its respective territories based on the results. Exelixis completed enrollment in August 2020 for this global phase 3 pivotal trial. Separately, patient enrollment remains open in China in order to enroll a sufficient number of patients to potentially enable local registration.
- **Metastatic castration-resistant prostate cancer (CRPC):** Should the data continue to be supportive, Exelixis anticipates filing an sNDA in 2021 seeking accelerated approval of cabozantinib in combination with atezolizumab, for the treatment of metastatic CRPC. A confirmatory phase 3 pivotal trial of this regimen in this patient population (CONTACT-02) was initiated in June 2020 under the clinical trial collaboration between Exelixis and Roche.

Additional Cabozantinib Clinical Updates

- **COSMIC-313:** Exelixis expanded the enrollment target to 840 patients to provide additional power to assess the secondary endpoint of OS for COSMIC-313, the phase 3 pivotal trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab (YERVOY®) versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC and expects to complete the expanded enrollment in early 2021. Top-line results of the event-driven analyses from the study are expected in 2022. If the data are supportive, the company would seek to file an sNDA with the FDA.
- **CONTACT trials:** In 2020, as part of a clinical trial collaboration between Exelixis and Roche, three phase 3 global pivotal trials were initiated evaluating the combination of cabozantinib and atezolizumab: CONTACT-01 in patients with metastatic non-small cell lung cancer who have been previously treated with an ICI and platinum-containing chemotherapy; CONTACT-02 in patients with metastatic CRPC who have been previously treated with one novel hormonal therapy; and CONTACT-03, in patients with inoperable, locally advanced or metastatic RCC who progressed during or following treatment with an ICI.

Anticipated Progress for XL092 and Other Compounds Beginning Clinical Development in 2021

- **XL092:** Exelixis is currently enrolling patients into the dose escalation cohorts of the phase 1b clinical trial of XL092 in combination with atezolizumab, and expects to initiate enrollment in the clear cell and non-clear cell RCC, hormone-receptor positive breast cancer and metastatic CRPC expansion cohorts shortly. The company also plans to initiate additional expansion cohorts in other tumor types, as well as potential additional studies, evaluating XL092 in combination with other oncology therapies, including ICIs. As data from these cohorts mature and are supportive, XL092 could enter pivotal trials over the course of 2021.
- **XL102:** Following the FDA's acceptance of its IND, Exelixis expects to initiate a phase 1 trial of XL102 (formerly known as AUR102), alone or in combination therapy for the treatment of inoperable, locally advanced or metastatic solid tumors. Exelixis in-licensed XL102 from Aurigene Discovery Technologies Limited in December 2020.
- **XB002:** Exelixis anticipates beginning a phase 1 trial of XB002 (formerly known as ICON-2), in patients with inoperable, locally advanced or metastatic solid tumors. Exelixis in-licensed XB002 from Iconic Therapeutics, Inc. in December 2020 and plans to file an IND once the drug product release assays are finalized.

- **Additional INDs planned:** Subject to preclinical data, Exelixis has the potential to file up to two additional INDs.

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 2020 financial results, 2021 financial guidance, and key priorities and milestones for 2021 during the company's presentation at the J.P. Morgan Healthcare Conference beginning at 5:20 p.m. EST / 2:20 p.m. PST on Monday, January 11, 2021.

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 90 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. In November 2020, the company was named to *Fortune*'s 100 Fastest-Growing Companies list for the first time, ranking 17th overall and the third-highest biopharmaceutical company. 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' anticipation of the FDA's approval and commercial launch of CABOMETYX for patients with advanced RCC as a first-line treatment in combination with Opdivo; Exelixis' 2021 financial guidance; the therapeutic and commercial potential of CABOMETYX and Exelixis' belief that it is well-positioned to deliver significant revenue growth throughout 2021 and beyond; Exelixis' intention to pursue additional regulatory approvals and clinical development activities that create the potential for a multi-billion dollar franchise; Exelixis' clinical development plans for XL092 and belief that it may ultimately become a source of long-term revenue; Exelixis' belief that it is well on its way to becoming a multi-product oncology company; Exelixis' corporate priorities and anticipated key milestones for 2021, including the potential filing of sNDAs for CABOMETYX in three additional indications, expanded clinical development activities for XL092, and multiple INDs for preclinical assets; Exelixis' estimate for CABOMETYX revenues in RCC exiting 2022; Exelixis' expectations for, and the related anticipated timelines for, completing enrollment in, conducting analyses of and obtaining top-line results from its ongoing potential label-enabling clinical studies evaluating cabozantinib, and if supported by the data, pursuing potential regulatory approvals; Exelixis' clinical development plans for XL102 and XB002; 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, risks and uncertainties associated with: 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, including evolving regulatory requirements, slower than anticipated patient enrollment or inability to identify a sufficient number of clinical trial sites; 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, including the risk that regulatory authorities may not approve Exelixis' products as treatments for the indications in which approval has been sought, if at all, as well as the related risk that regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of CABOMETYX in any additional indications or of any newly-approved product; 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 filed with the Securities and Exchange Commission (SEC) on November 5, 2020, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Annual Report on Form 10-K expected to be filed with the SEC on February 10, 2021. 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 January 1, 2021. Exelixis is currently in the process of finalizing its full financial results for the quarter and fiscal year ended January 1, 2021, and the preliminary financial results presented in this press release are based only upon preliminary information available to Exelixis as of January 10, 2021. 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 January 1, 2021.

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