Exelixis Announces First Quarter 2021 Financial Results and Provides Corporate Update

May 6, 2021

- Total Revenues of $270.2 Million, Cabozantinib Franchise Revenues of $227.2 Million -

- Conference Call and Webcast Today at 5:00 PM Eastern Time -

ALAMEDA, Calif.--(BUSINESS WIRE)--May 6, 2021-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2021 and provided an update on progress toward achieving key corporate objectives, as well as commercial, clinical and pipeline development milestones.

"The Exelixis team made significant progress across all components of our business in the first quarter of 2021, and delivered top-line revenue growth following the U.S. approval of CABOMETYX® in combination with OPDIVO® for first-line renal cell carcinoma in late January," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "We also executed on a number of key priorities throughout the quarter, including initiating phase 1 clinical development of XL102, our novel small molecule CDK7 inhibitor, and successfully filing an Investigational New Drug application with the FDA for XB002, our first antibody-drug conjugate. We continue to focus on key 2021 development and regulatory milestones, and expect to report top-line results in the second quarter from the phase 3 COSMIC-312 pivotal trial evaluating the combination of cabozantinib and atezolizumab as a first-line treatment in advanced hepatocellular carcinoma, and file up to three supplemental New Drug Applications for cabozantinib across multiple indications by year-end. I look forward to providing updates on our progress throughout the year as we further our efforts to build a leading multi-product oncology company aiming to deliver new therapies and treatment options for the patients we serve."

First Quarter 2021 Financial Results

Total revenues for the quarter ended March 31, 2021 were $270.2 million, compared to $226.9 million for the comparable period in 2020.

Total revenues for the quarter ended March 31, 2021 included net product revenues of $227.2 million, compared to $193.9 million for the comparable period in 2020. The increase in net product revenues was primarily related to an increase in sales volume that was partially driven by strong uptake for the combination therapy of CABOMETYX® (cabozantinib) and OPDIVO® (nivolumab) following approval by the U.S. Food and Drug Administration (FDA) in January of 2021.

Collaboration revenues, composed of license revenues and collaboration services revenues, were $43.0 million for the quarter ended March 31, 2021, compared to $33.0 million for the comparable period in 2020. The increase in collaboration revenues was primarily related to higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis' collaboration partners, Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda), and increases in development cost reimbursements.

Research and development expenses for the quarter ended March 31, 2021 were $159.3 million, compared to $101.9 million for the comparable period in 2020. The increase in research and development expenses was primarily related to increases in license and other collaboration costs, clinical trial costs, personnel expenses and stock-based compensation expense.

Selling, general and administrative expenses for the quarter ended March 31, 2021 were $102.4 million, compared to $62.9 million for the comparable period in 2020. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses, marketing costs, corporate giving and stock-based compensation expense, which was partially offset by a decrease in the Branded Prescription Drug Fee.

Provision for (benefit from) income taxes for the quarter ended March 31, 2021 was $(3.6) million, compared to $11.4 million for the comparable period in 2020, primarily due to the change in pre-tax income (loss).

GAAP net income for the quarter ended March 31, 2021 was $1.6 million, or $0.01 per share, basic and $0.00 per share, diluted, compared to GAAP net income of $48.6 million, or $0.16 per share, basic and $0.15 per share, diluted, for the comparable period in 2020.

Non-GAAP net income for the quarter ended March 31, 2021 was $28.5 million, or $0.09 per share, basic and diluted, compared to non-GAAP net income of $59.4 million, or $0.19 per share, basic and diluted, for the comparable period in 2020. Non-GAAP net income excludes stock-based compensation, adjusted for the related income tax effect.

Cash, cash equivalents, restricted cash equivalents and investments were $1.6 billion at March 31, 2021, compared to $1.5 billion at December 31, 2020.

Non-GAAP Financial Measures

To supplement Exelixis' financial results presented in accordance with U.S. Generally Accepted Accounting Principles (GAAP), Exelixis presents non-GAAP net income (and the related per share measures), which excludes from GAAP net income (and the related per share measures) stock-based compensation expense, adjusted for the related income tax effect for all periods presented.

Exelixis believes that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, Exelixis believes that these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Exelixis' results from period to period, and to identify operating trends in Exelixis' business. Exelixis has excluded stock-based compensation expense, adjusted for the related income tax effect, because it is a non-cash item that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented. Exelixis also regularly uses these non-GAAP financial measures internally to understand, manage

and evaluate its business and to make operating decisions.

These non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Exelixis encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations, to more fully understand Exelixis' business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

2021 Financial Guidance

Exelixis is maintaining the following previously provided financial guidance for fiscal year 2021:

Total revenues	$1,150 million - $1,250 million
Net product revenues	$950 million - $1,050 million
Cost of goods sold	Approximately 5% - 6% of net product revenue
Research and development expenses (1)	$600 million - $650 million
Selling, general and administrative expenses (2)	$375 million - $425 million
Effective tax rate	20% - 22%
Cash and investments (3)(4)	$1.6 billion - $1.7 billion

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

(2) Includes $60 million of non-cash stock-based compensation expense.

(3) This cash and investments guidance does not include any potential new business development activity.

(4) Cash and Investments is composed of cash, cash equivalents, restricted cash equivalents and investments.

Cabozantinib Highlights

Cabozantinib Franchise Net Product Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were $227.2 million during the first quarter of 2021, up 13 percent over the prior quarter, with net product revenues of $223.6 million from CABOMETYX and $3.6 million from COMETRIQ® (cabozantinib). Exelixis earned $23.8 million in royalty revenues during the quarter ended March 31, 2021, pursuant to collaboration agreements with our partners, Ipsen and Takeda.

FDA Approves CABOMETYX in Combination with OPDIVO for Advanced Renal Cell Carcinoma (RCC). In January 2021, Exelixis announced the FDA approved its supplemental New Drug Application (sNDA) for CABOMETYX in combination with Bristol Myers Squibb's OPDIVO as a first-line treatment of patients with advanced RCC. The approval is based on positive results of the CheckMate -9ER phase 3 pivotal trial, which met its primary endpoint of significantly improving progression-free survival (PFS) and secondary endpoints of overall survival (OS) and objective response rate (ORR), with a favorable tolerability profile versus sunitinib.

Cabozantinib Data Presentations Demonstrate Broad Anti-Tumor Activity at the 2021 American Society of Clinical Oncology's Genitourinary Cancers Symposium (ASCO GU 2021). In February 2021, cabozantinib was the subject of multiple data presentations at ASCO GU 2021, held virtually from February 11-13. Presentations included: updated trial results with extended follow-up and patient-reported outcomes from the CheckMate -9ER trial demonstrating continued superior PFS, OS and ORR versus sunitinib across both the subgroup of 75 patients with sarcomatoid histology and the full study population, as well as significantly improved health-related quality of life; positive results from the SWOG S1500 trial ("PAPMET") of cabozantinib versus sunitinib in metastatic papillary RCC; positive findings from an international retrospective study of cabozantinib in RCC patients with brain metastases; and positive final results from the phase 1 trial sponsored and conducted by NCI-CTEP, including seven expansion cohorts, evaluating cabozantinib in combination with either nivolumab or nivolumab plus ipilimumab in patients with refractory metastatic genitourinary tumors.

FDA Grants Breakthrough Therapy Designation to Cabozantinib for the Treatment of Patients with Previously Treated Radioactive Iodine-Refractory Differentiated Thyroid Cancer (DTC). In February 2021, Exelixis announced that the FDA granted Breakthrough Therapy Designation to cabozantinib as a potential treatment for patients with DTC who progressed following prior therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). The FDA's Breakthrough Therapy Designation aims to expedite the development and review of drugs that are intended to treat serious or life-threatening diseases. The designation was based on an interim analysis of the COSMIC-311 phase 3 pivotal trial, in which cabozantinib demonstrated significant improvement in PFS.

Exelixis' Partner Ipsen Receives European Commission (EC) Approval for CABOMETYX in Combination with OPDIVO as First-Line Treatment for Patients with Advanced RCC. In March 2021, Exelixis announced its partner Ipsen received approval from the EC for CABOMETYX in combination with OPDIVO as a first-line treatment for advanced RCC. The approval allows for the marketing of CABOMETYX in combination with OPDIVO in this indication in all 27 member states of the European Union, Norway, Iceland and Liechtenstein. The EC approval was based on the positive results of the phase 3 CheckMate -9ER pivotal trial.

Enrollment Completed in Phase 3 COSMIC-313 Pivotal Trial of Cabozantinib in Combination with Nivolumab and Ipilimumab Versus Nivolumab and Ipilimumab in Previously Untreated Advanced RCC. In March 2021, Exelixis announced that 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, completed enrollment. COSMIC-313 is a multicenter, randomized, double-blind, controlled phase 3 pivotal trial that enrolled approximately 840 patients globally. The primary endpoint of the trial is PFS, and additional endpoints include OS and ORR.

Cabozantinib Data Presentations at the 2021 ASCO Annual Meeting. Cabozantinib will be the subject of 20 presentations at this year's meeting, which has again adopted a virtual format as a result of the COVID-19 pandemic. Data presentations will include results from the COSMIC-311 and CheckMate -9ER phase 3 pivotal trials, as well as updates from externally sponsored studies.

Pipeline Highlights

Initiation of Phase 1 Clinical Trial Evaluating XL102 as a Single Agent and in Combination with Other Anti-Cancer Agents in Patients with Advanced or Metastatic Solid Tumors. In January 2021, Exelixis announced the initiation of a phase 1 clinical trial evaluating the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of XL102, both as a single agent and in combination with other anti-cancer agents, for the treatment of patients with inoperable, locally advanced or metastatic solid tumors. XL102 (formerly AUR102) is a potent, selective and orally bioavailable inhibitor of cyclin-dependent kinase 7 (CDK7) that Exelixis in-licensed from Aurigene Discovery Technologies Limited in December 2020 under the companies' July 2019 collaboration agreement.

FDA Accepts Investigational New Drug Application (IND) for Tissue Factor-Targeting Antibody-Drug Conjugate (ADC) XB002 in Patients with Advanced Solid Tumors. In April 2021, Exelixis announced that the FDA accepted its IND to evaluate the safety, tolerability, pharmacokinetics and preliminary antitumor activity of XB002 in patients with advanced solid tumors. As a next-generation tissue factor-targeting ADC, XB002 (formerly ICON-2) has the potential for an improved therapeutic index and may provide a favorable safety profile compared with earlier-generation tissue factor-targeting ADCs. Exelixis in-licensed XB002 from Iconic Therapeutics, Inc. in December 2020 under the companies' May 2019 collaboration agreement.

Corporate Updates

Exelixis Outlines Key Priorities and Anticipated Milestones for 2021. In January 2021, Exelixis announced its key priorities and anticipated milestones for 2021, including: the commercial launch of CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC; potential sNDA submissions for CABOMETYX in DTC, hepatocellular carcinoma and metastatic castration-resistant prostate cancer; progress and enrollment in the COSMIC and CONTACT clinical studies evaluating cabozantinib as a single agent or in combination with immune checkpoint inhibitors (ICIs); expanded clinical development activities for XL092; and multiple INDs for preclinical assets. Exelixis presented the details of its key priorities and anticipated milestones at the 39th Annual J.P. Morgan Healthcare Conference, which was held virtually from January 11-14.

Exelixis and Adagene Inc. (Adagene) Enter into Collaboration and License Agreement to Develop Novel Masked ADC Therapies with Improved Safety and Efficacy Profiles. In February 2021, Exelixis and Adagene announced a collaboration and license agreement under which Exelixis will utilize Adagene's SAFEbody™ technology platform to generate masked versions of monoclonal antibodies (mAbs) from Exelixis' growing preclinical pipeline for the development of SAFEbodies or other innovative biologics against Exelixis-nominated targets. Under the terms of the agreement, Exelixis received an exclusive, worldwide license to develop and commercialize any potential ADC products generated by Adagene with respect to an initial target, as well as a second target Exelixis may nominate during the collaboration term.

Exelixis Enters into Exclusive License Agreement with WuXi Biologics (WuXi Bio) to Support Further Expansion of its Growing Oncology Biologics Pipeline. In March 2021, Exelixis announced an exclusive license agreement with WuXi Bio to support the continued expansion of Exelixis' oncology biologics pipeline. Under the terms of the agreement, Exelixis received an exclusive license to a panel of mAbs to a validated target, discovered based on WuXi Bio's integrated technology platforms, for the development of ADC, bispecific, and certain other novel tumor-targeting biologics applications.

Exelixis Enters Clinical Trial Collaboration and Supply Agreement with Merck KGaA, Darmstadt, Germany (Merck KGaA) and Pfizer Inc. (Pfizer) to Evaluate XL092 and Avelumab (BAVENCIO®) in Various Forms of Locally Advanced or Metastatic Urothelial Carcinoma (UC). In March 2021, Exelixis announced a clinical trial collaboration and supply agreement with Merck KGaA and Pfizer for the ongoing phase 1b dose escalation study STELLAR-001 (previously called "XL092-001"), adding three new cohorts that will evaluate the safety and tolerability of XL092, Exelixis' novel next generation tyrosine kinase inhibitor, in combination with avelumab, an anti-PD-L1 ICI, in patients with locally advanced or metastatic UC.

Exelixis Expands its Biotherapeutics Portfolio with Acquisition of Anti-Müllerian Hormone Receptor 2 (AMHR2) Program from GamaMabs Pharma SA (GamaMabs). In May 2021, Exelixis entered into an asset purchase agreement with GamaMabs under which Exelixis will, upon the closing of the asset purchase and subject to certain conditions, acquire all rights, title and interest in GamaMabs' antibody program directed at AMHR2, a novel oncology target with relevance in multiple forms of cancer. Exelixis believes applying its ADC capabilities to GamaMabs' panel of antibodies against AMHR2 could yield potential additions to the company's biotherapeutics portfolio.

Exelixis Receives Notice of Paragraph IV Certifications. In May 2021, Exelixis received a notice letter from Teva Pharmaceuticals USA, Inc. (Teva) regarding an Abbreviated New Drug Application Teva submitted to the FDA, requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letter included a Paragraph IV certification with respect to three of Exelixis' Orange Book-listed patents: U.S. Patent Nos. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which expire in 2033, 2031 and 2031, respectively. Teva's notice letter did not provide a Paragraph IV certification against any additional CABOMETYX patents. Exelixis intends to continue to vigorously defend its cabozantinib intellectual property estate.

Basis of Presentation

Exelixis has adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. For convenience, references in this press release as of and for the fiscal periods ended April 2, 2021, January 1, 2021 and April 3, 2020 are indicated as being as of and for the periods ended March 31, 2021, December 31, 2020, and March 31, 2020, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the first quarter of 2021 and provide a general business update during a conference call beginning at 5:00 p.m. EDT / 2:00 p.m. PDT today, Thursday, May 6, 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 conference call to ensure adequate time for any software download that may be required to listen to the webcast. Alternatively, please call 855-793-2457 (domestic) or 631-485-4921 (international) and provide the conference call passcode 6139476 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on May 8, 2021. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 6139476. A webcast replay will also be archived on www.exelixis.com for one year.

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

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' expectations regarding key development and regulatory milestones in 2021; Exelixis' efforts to build a leading multi-product oncology company; Exelixis' 2021 financial guidance; planned cabozantinib presentations at the 2021 ASCO Annual Meeting; the therapeutic potential of XB002; Exelixis' key priorities and anticipated milestones for 2021; the potential expansion of Exelixis' biotherapeutics portfolio as a result of the GamaMabs AMHR2 program acquisition; and 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. 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' Annual Report on Form 10-K submitted to the Securities and Exchange Commission (SEC) on February 10, 2021, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Quarterly Report on Form 10-Q expected to be filed with the SEC on May 6, 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.

-see attached financial tables-

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Revenues:		
Net product revenues	$ 227,212	$ 193,880
License revenues	27,528	20,879
Collaboration services revenues	15,490	12,156
Total revenues	270,230	226,915
Operating expenses:		
Cost of goods sold	13,198	9,289

Research and development	159,288	101,877
Selling, general and administrative	102,351	62,940
Total operating expenses	274,837	174,106
Income (loss) from operations	(4,607)	52,809
Interest income	2,682	7,220
Other income (expense), net	(90)	6
Income (loss) before income taxes	(2,015)	60,035
Provision for (benefit from) income taxes	(3,616)	11,423
Net income	$ 1,601	$ 48,612
Net income per share:		
Basic	$ 0.01	$ 0.16
Diluted	$ 0.00	$ 0.15
Weighted-average common shares outstanding:		
Basic	312,473	305,388
Diluted	321,287	315,839

EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEET DATA
(in thousands)
(unaudited)

	March 31, 2021	December 31, 2020
Cash and investments [1]	$ 1,564,066	$ 1,538,842
Working capital	$ 1,220,928	$ 1,240,737
Total assets	$ 2,190,542	$ 2,137,333
Total stockholders' equity	$ 1,911,187	$ 1,879,113

(1) Cash and Investments is composed of cash, cash equivalents, restricted cash equivalents and investments.

EXELIXIS, INC.
RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2021	2020
GAAP net income	$ 1,601	$ 48,612
Adjustments:		
Stock-based compensation - research and development expenses [1]	12,396	5,086
Stock-based compensation - selling, general and administrative expenses [1]	22,257	8,896
Income tax effect of the above adjustments	(7,789)	(3,180)
Non-GAAP net income	$ 28,465	$ 59,414
GAAP net income per share:		
Basic	$ 0.01	$ 0.16
Diluted	$ 0.00	$ 0.15
Non-GAAP net income per share:		
Basic	$ 0.09	$ 0.19
Diluted	$ 0.09	$ 0.19
Weighted-average common shares outstanding:		
Basic	312,473	305,388
Diluted	321,287	315,839

(1) Non-cash stock-based compensation expense used for GAAP reporting in accordance with Accounting Standards Codification Topic 718, *Compensation—Stock Compensation*.

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