Exelixis Announces First Quarter 2019 Financial Results and Provides Corporate Update

May 1, 2019

- Total Revenue of $215.5 Million, Cabozantinib Franchise Revenue of $179.6 Million -

- GAAP Diluted EPS of $0.24, Non-GAAP Diluted EPS of $0.27 -

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

ALAMEDA, Calif.--(BUSINESS WIRE)--May 1, 2019-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2019 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

"The first quarter of 2019 was a very productive start to the year, with strong execution across all aspects of our business," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "We continued our efforts to maximize the commercial and clinical potential of cabozantinib through the U.S. launch in advanced hepatocellular cancer in January, as well as the initiation of the COSMIC-313 study announced today."

Dr. Morrissey continued: "The financial stability provided by our growing revenue base across product and collaboration revenue provides Exelixis with an effective foundation upon which to pursue long-term growth. We have ambitious plans for the rest of 2019: we intend to start additional cabozantinib pivotal trials, bring new assets into our development organization through internal drug discovery and external business development, and advance our early-stage pipeline, including XL092. As we move through our 25th anniversary year, not only is our commitment to helping patients with cancer stronger than ever, but our ability to do so is notably stronger as well."

First Quarter 2019 Financial Results

Total revenues for the quarter ended March 31, 2019 were $215.5 million, compared to $213.7 million for the comparable period in 2018.

Total revenues included net product revenues of $179.6 million for the quarter ended March 31, 2019, compared to $134.3 million for the comparable period in 2018. The increase in net product revenues reflected the continued growth of CABOMETYX® (cabozantinib) in the U.S. for the treatment of patients with advanced renal cell carcinoma (RCC), as well as the U.S. launch of CABOMETYX for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib, following its approval by the U.S. Food and Drug Administration (FDA) in January 2019.

CABOMETYX net product revenues for the quarter ended March 31, 2019 were $175.9 million, compared to $171.6 million for the quarter ended December 31, 2018. CABOMETYX net product revenues, as compared to the preceding quarter, were impacted by higher discounts and allowances of $7.2 million, driven by increased uptake in the government payor channel. In addition, as of March 31, 2019, the quantity of CABOMETYX inventory in the U.S. wholesaler distribution channel was approximately $2.3 million lower than it was as of December 31, 2018.

Total revenues for the quarter ended March 31, 2019 also include collaboration revenues of $35.9 million, compared to $79.4 million for the comparable period in 2018. The decrease in collaboration revenues was primarily the result of a decrease in revenues from milestones recognized from Exelixis' collaboration agreements, which was partially offset by increases in royalty revenues on net sales of cabozantinib by Ipsen Pharma SAS (Ipsen) outside of the U.S. and Japan, and development cost reimbursements by Ipsen and Takeda Pharmaceutical Company Ltd. (Takeda).

Research and development expenses for the quarter ended March 31, 2019 were $63.3 million, compared to $37.8 million for the comparable period in 2018. The increase in research and development expenses was primarily related to increases in clinical trial costs, personnel expenses and stock-based compensation. The increase in clinical trial costs was primarily due to costs associated with the expanding clinical trial program for cabozantinib that now includes four phase 3 pivotal studies (CheckMate 9ER, COSMIC-311, COSMIC-312 and COSMIC-313), as well as the multi-cohort phase 1b study, COSMIC-021. The increases in personnel expenses and stock-based compensation were primarily due to increases in headcount to support Exelixis' expanded discovery and development efforts.

Selling, general and administrative expenses for the quarter ended March 31, 2019 were $60.1 million, compared to $54.0 million for the comparable period in 2018. The increase in selling, general and administrative expenses was primarily related to increases in consulting and outside services, personnel expenses, marketing costs and stock-based compensation. The increases in personnel expenses and stock-based compensation were primarily due to increases in general and administrative headcount to support the company's commercial and research and development organizations. The increase in consulting and outside services and marketing expenses was primarily due to increases in marketing activities in support of the CABOMETYX launch in HCC and continued support of the product in an increasingly competitive RCC market.

Provision for income taxes for the quarter ended March 31, 2019 was $14.9 million and Exelixis' effective tax rate was 16.4%, compared to $2.5 million and 2.1%, respectively, for the comparable period in 2018. The provision for income taxes relating to Exelixis' pre-tax income for the three months ended March 31, 2018 was largely offset by a valuation allowance against its net operating loss carryforwards and other deferred tax assets. At December 31, 2018, Exelixis released substantially all of the remaining valuation allowance against Exelixis' deferred tax assets, after Exelixis determined that it was more likely than not that these deferred tax assets would be realized.

GAAP net income for the quarter ended March 31, 2019 was $75.8 million, or $0.25 per share, basic and $0.24 per share, diluted, compared to

GAAP net income of $115.9 million, or $0.39 per share, basic and $0.37 per share, diluted, for the comparable period in 2018. The decrease in net income was primarily related to the decrease in milestone-related revenues and the increases in research and development expenses, selling, general and administrative expenses and the provision for income taxes; those changes were partially offset by the increases in net product revenues and royalty revenues recognized from Exelixis' collaboration agreements.

Non-GAAP net income for the quarter ended March 31, 2019 was $85.5 million, or $0.28 per share, basic and $0.27 per share, diluted, compared to non-GAAP net income of $125.0 million, or $0.42 per share, basic and $0.40 per share, diluted, for the comparable period in 2018. Non-GAAP net income excludes stock-based compensation and adjusts for the related income tax effect.

Cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments totaled $1,019.4 million at March 31, 2019, compared to $851.6 million at December 31, 2018.

Non-GAAP Financial Measures

To supplement Exelixis' financial results presented in accordance with GAAP, Exelixis uses certain non-GAAP financial measures in this press release. In particular, Exelixis presents non-GAAP net income (and the related per share measures), which exclude from GAAP net income (and the related per share measures) stock-based compensation expense and adjust for the related income tax effect of this non-GAAP adjustment.

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 each of 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 because it is a non-cash expense 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.

2019 Financial Guidance

Exelixis is maintaining the following financial guidance for 2019. Cost of goods sold is expected to be between 4% and 5% of net product revenues. Research and development expenses are expected to be between $285 million and $315 million and include non-cash expenses related to stock-based compensation of $20 million. Selling, general and administrative expenses are expected to be between $220 million and $240 million and include non-cash expenses related to stock-based compensation of $35 million. Guidance for the effective tax rate in 2019 is between 21% and 23%.

Cabozantinib Highlights

Strong Growth in Cabozantinib Franchise Net Revenues and Royalties. Net product revenues generated by the cabozantinib franchise were $179.6 million during the quarter ended March 31, 2019, an increase of 34% year-over-year. During the first quarter of 2019, CABOMETYX generated $175.9 million in net product revenues and COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional $3.7 million in net product revenues. Based upon our partner Ipsen's cabozantinib-related revenues in the first quarter of 2019 of approximately $63 million, Exelixis earned $14.0 million in royalty revenues at the 22% royalty rate. CABOMETYX continues to expand its global footprint, where it is currently approved and commercially available in 41 and 28 countries, respectively.

FDA Approval of CABOMETYX Tablets for Previously Treated HCC. In January, Exelixis announced the FDA approval of CABOMETYX for the treatment of patients with HCC who have been previously treated with sorafenib. The FDA's approval of CABOMETYX was based on results from the CELESTIAL phase 3 pivotal trial.

Cabozantinib Data at the 2019 American Society for Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI). In January, data from clinical trials of cabozantinib were featured in five presentations at ASCO-GI in San Francisco, including further analyses from the CELESTIAL trial.

Takeda's Application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for CABOMETYX as a Treatment for Advanced RCC. In April, Takeda, Exelixis' partner in cabozantinib's development and commercialization in Japan, announced that it applied to the Japanese MHLW for approval to manufacture and sell CABOMETYX as a treatment for unresectable and metastatic RCC in Japan. Per the terms of the exclusive licensing agreement the two companies entered into in 2017, Exelixis will receive a $10.0 million milestone payment as a result of this regulatory filing. Exelixis is eligible for additional development, regulatory and first-sales milestone payments, as well as royalties on sales of cabozantinib in Japan.

Completion of Enrollment in CheckMate 9ER. In April, CheckMate 9ER, the phase 3 pivotal trial evaluating the combination of cabozantinib and nivolumab versus sunitinib in patients with previously untreated advanced or metastatic RCC completed enrollment, including in Japan where the last few patients are in the process of being randomized. CheckMate 9ER is sponsored by Bristol-Myers Squibb Company (BMS) and co-funded by Exelixis, and Exelixis' partners Ipsen and Takeda.

Initiation of COSMIC-313, 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. Today, Exelixis announced the initiation of COSMIC-313, a multicenter, randomized, double-blinded, controlled phase 3 pivotal trial that aims to enroll approximately 676 patients at 150 sites globally. The primary endpoint of the trial is progression-free survival, and the secondary endpoints are overall survival and objective response rate. COSMIC-313 will be conducted in collaboration with BMS, which is providing nivolumab and ipilimumab for use in this trial.

Corporate Highlights

MINNEBRO ™ Receives Regulatory Approval for the Treatment of Hypertension in Japan. In January, Exelixis' partner Daiichi Sankyo Company, Limited (Daiichi Sankyo) announced that MINNEBRO ™ (esaxerenone) tablets had received approval from the Japanese MHLW as a treatment for

patients with hypertension. MINNEBRO is a compound identified during the prior research collaboration between Exelixis and Daiichi Sankyo, which the companies entered into in March 2006, and has been subsequently developed by Daiichi Sankyo. Per the collaboration agreement, Exelixis will receive a $20.0 million milestone payment upon the first commercial sale of MINNEBRO in Japan. Exelixis is eligible for additional commercialization milestone payments, as well as low double-digit royalties on sales of MINNEBRO.

Start of Phase 1 Development for XL092. In February, Exelixis announced it had submitted an investigational new drug (IND) application to the FDA for XL092, a next-generation small molecule tyrosine kinase inhibitor targeting VEGF receptors, MET and other kinases implicated in cancer's growth and spread. Following the FDA's acceptance of the IND filing, Exelixis initiated a phase 1 dose escalation trial evaluating the pharmacokinetics, safety and tolerability of XL092 in patients with advanced solid tumors, with the primary objective of determining a dose for daily oral administration of XL092 suitable for further evaluation. Assuming positive data from the initial phase of the trial, the expansion phase is designed to further explore the selected dose of XL092 in individual tumor cohorts, where safety, tolerability and initial clinical activity would be evaluated. XL092 is the first clinical candidate to emerge from Exelixis' in-house laboratories since Exelixis resumed drug discovery activities.

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 March 29, 2019, December 28, 2018 and March 30, 2018 are indicated as being as of and for the periods ended March 31, 2019, December 31, 2018 and March 31, 2018, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the first quarter of 2019 and provide a general business update during a conference call beginning at 5:00 p.m. EDT / 2:00 p.m. PDT today, Wednesday, May 1, 2019.

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 4774486 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on May 3, 2019. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 4774486. 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 genetic systems, 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 approved 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 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

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' ambitious plans for the rest of 2019, including Exelixis' intention to start additional cabozantinib pivotal trials, bring new assets into Exelixis' development organization through internal drug discovery and external business development, and advance Exelixis' early-stage pipeline, including XL092; Exelixis' guidance for 2019 cost of goods sold, research and development expenses (including non-cash expenses related to stock-based compensation), selling, general and administrative expenses (including non-cash expenses related to stock-based compensation), and effective tax rate; Exelixis' receipt of a $10.0 million milestone payment from Takeda for Takeda's submission of an application to the Japanese MHLW for approval to manufacture and sell CABOMETYX as a treatment for unresectable and metastatic RCC in Japan; Exelixis' eligibility for additional development, regulatory and first-sale milestone payments, as well as royalties on sales under its collaboration with Takeda; the anticipated timing for receipt of a $20.0 million milestone payment from Daiichi Sankyo upon the first commercial sale of MINNEBRO in Japan; Exelixis' eligibility for additional commercialization milestone payments, as well as low double-digit royalties on sales of MINNEBRO; Exelixis' plans for further explorations of XL092 in the expansion phase of the phase 1 dose escalation trial should data from the initial phase prove positive; 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 degree of market acceptance of CABOMETYX, COMETRIQ, COTELLIC and MINNEBRO in the territories where they are approved, and Exelixis' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX, COMETRIQ, COTELLIC and MINNEBRO 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; the potential failure of cabozantinib, cobimetinib, esaxerenone 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; risks and uncertainties related to regulatory review and approval processes, including that regulatory authorities may not approve Exelixis' products as treatments for the indications in which approval has been sought; 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, cobimetinib or esaxerenone; Exelixis' dependence on third-party vendors for the manufacture and supply of its products; 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 filed with the Securities and Exchange Commission (SEC) on February 22, 2019, 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 1, 2019. 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.

EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
Net product revenues	$ 179,581	$ 134,272
Collaboration revenues	35,906	79,447
Total revenues	215,487	213,719
Operating expenses:		
Cost of goods sold	7,501	5,639
Research and development	63,289	37,757
Selling, general and administrative	60,138	54,016
Total operating expenses	130,928	97,412
Income from operations	84,559	116,307
Other income (expense), net:		
Interest income	6,087	1,895
Other, net	25	169
Total other income (expense), net	6,112	2,064
Income before income taxes	90,671	118,371
Provision for income taxes	(14,896)	(2,514)
Net income	$ 75,775	$ 115,857
Net income per share, basic	$ 0.25	$ 0.39
Net income per share, diluted	$ 0.24	$ 0.37
Shares used in computing net income per share, basic	300,542	296,421
Shares used in computing net income per share, diluted	314,644	313,691

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

(unaudited)

	March 31, 2019	**December 31, 2018 (1)**
Cash and investments (2)	$ 1,019,369	$ 851,621
Working capital	$ 821,166	$ 791,544
Total assets	$ 1,541,794	$ 1,422,286
Total stockholders' equity	$ 1,385,020	$ 1,287,453

(1) Derived from the audited consolidated financial statements.

(2) Cash and investments include cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments. Long-term restricted cash and investments totaled $1.1 million as of March 31, 2019 and December 31, 2018.

EXELIXIS, INC.

RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2019	**2018**
GAAP net income	$ 75,775	$ 115,857
Adjustments:		
Stock-based compensation - research and development expenses	4,306	3,033
Stock-based compensation - selling, general and administrative expenses	8,223	6,272
Income tax effect of the above adjustments	(2,809)	(200)
Non-GAAP net income	$ 85,495	$ 124,962
GAAP net income per share, basic	$ 0.25	$ 0.39
GAAP net income per share, diluted	$ 0.24	$ 0.37
Non-GAAP net income per share, basic	$ 0.28	$ 0.42
Non-GAAP net income per share, diluted	$ 0.27	$ 0.40
Shares used in computing net income per share, basic	300,542	296,421
Shares used in computing net income per share, diluted	314,644	313,691

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