Exelixis Announces Second Quarter 2019 Financial Results and Provides Corporate Update

July 31, 2019

- Total Revenue of $240.3 Million, Cabozantinib Franchise Revenue of $193.7 Million -

- GAAP Diluted EPS of $0.25, Non-GAAP Diluted EPS of $0.29 -

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

ALAMEDA, Calif.--(BUSINESS WIRE)--Jul. 31, 2019-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2019 and provided an update on progress toward fulfilling its key corporate objectives, as well as discovery, development and commercial milestones.

"The second quarter of 2019 was highlighted by the strong and sustained momentum of our business," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "We achieved notable revenue growth for the CABOMETYX franchise, supporting our strategy of reinvestment in long-term growth opportunities through our internal discovery and targeted in-licensing activities, including today's announcement of our partnership agreement with Aurigene."

Dr. Morrissey continued: "Our clinical development efforts continue to accelerate with the initiation of COSMIC-313, a new phase 3 pivotal trial of the cabozantinib triplet combination with nivolumab and ipilimumab in renal cell carcinoma, as well as the recent expansion of COSMIC-021, our phase 1b trial of cabozantinib and atezolizumab across multiple tumor types. Through the rest of our 25th anniversary year, we're working to advance our business with a focus on sustainable long-term growth through commercial execution, thoughtful research and development investments, and financial discipline."

Second Quarter 2019 Financial Results

Total revenues for the quarter ended June 30, 2019 were $240.3 million, compared to $186.1 million for the comparable period in 2018.

Total revenues included net product revenues of $193.7 million for the quarter ended June 30, 2019, compared to $145.8 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 who have been previously treated with sorafenib, following its approval by the U.S. Food and Drug Administration in January 2019.

Total revenues for the quarter ended June 30, 2019 also include collaboration revenues of $46.6 million, compared to $40.3 million for the comparable period in 2018. The increase in collaboration revenues was primarily the result of the recognition of a $20.0 million milestone from Daiichi Sankyo Company, Limited (Daiichi Sankyo) for the launch of MINNEBRO® (esaxerenone) tablets as a treatment for patients with hypertension in Japan, 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), offset by a $25.0 million milestone from Ipsen recognized in the comparable period in 2018 for the achievement of $100.0 million of net sales cumulatively over four consecutive fiscal quarters.

Research and development expenses for the quarter ended June 30, 2019 were $81.9 million, compared to $42.5 million for the comparable period in 2018. The increase in research and development expenses was primarily related to increases in clinical trial costs, license and other collaboration 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 includes four phase 3 pivotal studies (CheckMate 9ER, COSMIC-311, COSMIC-312 and COSMIC-313), as well as a multi-cohort phase 1b study (COSMIC-021). The increase in license and other collaboration costs was primarily a result of the collaboration and license agreement Exelixis entered into with Iconic Therapeutics, Inc. (Iconic) in May 2019. The increase in personnel expenses was primarily due to increases in headcount to support Exelixis' expanded discovery and development efforts. The increase in stock-based compensation was primarily due to increases in headcount, as well as the expense recognition attributable to research and development for restricted stock units that were granted in September 2018 that will vest upon the achievement of specific performance targets (the PSUs).

Selling, general and administrative expenses for the quarter ended June 30, 2019 were $58.8 million, compared to $51.9 million for the comparable period in 2018. The increase in selling, general and administrative expenses was primarily related to increases in stock-based compensation and personnel expenses. The increase in stock-based compensation was primarily due to increases in general and administrative headcount to support the company's commercial and research and development organizations as well as the expense recognition attributable to selling, general and administrative for the PSUs. The increase in personnel expenses was primarily due to increases in headcount.

Provision for income taxes for the quarter ended June 30, 2019 was $20.7 million and Exelixis' effective tax rate was 20.8%, compared to $0.9 million and 1.0%, respectively, for the comparable period in 2018. The provision for income taxes relating to Exelixis' pre-tax income for the three months ended June 30, 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 June 30, 2019 was $79.0 million, or $0.26 per share, basic and $0.25 per share, diluted, compared to GAAP net income of $87.5 million, or $0.29 per share, basic and $0.28 per share, diluted, for the comparable period in 2018. The decrease in net income was primarily related to 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 both net product revenues and collaboration revenues recognized from Exelixis' collaboration agreements.

Non-GAAP net income for the quarter ended June 30, 2019 was $90.7 million, or $0.30 per share, basic and $0.29 per share, diluted, compared to non-GAAP net income of $96.6 million, or $0.32 per share, basic and $0.31 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 investments totaled $1,161.0 million at June 30, 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 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 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 providing the following updated financial guidance for the full year 2019. Cost of goods sold is expected to be between 4% and 5% of net product revenues. Research and development expenses are now expected to be between $330 million and $350 million given the impact of the recent business development activities and include non-cash expenses related to stock-based compensation of $25 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 $40 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 $193.7 million during the second quarter of 2019, an increase of 32.8% year-over-year. During the second quarter of 2019, CABOMETYX generated $189.0 million in net product revenues and COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated $4.7 million in net product revenues. Based upon Exelixis' partner Ipsen's cabozantinib-related revenues in the second quarter of 2019 of approximately $67 million, Exelixis earned $14.9 million in royalty revenues at the 22% royalty rate. The commercial rollout of CABOMETYX continues globally, where it is now approved and commercially available in 45 and 33 countries, respectively.

Takeda Submits Marketing Application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for CABOMETYX as a Treatment for 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. In May, Exelixis and Takeda amended the agreement originally executed in 2017. Per the terms of the amended agreement, as a result of this regulatory filing, Exelixis received a milestone payment in the second quarter of 2019 of $16.0 million, $9.4 million of which was recognized as revenue on the Company's income statement in the first quarter of 2019. 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 May, CheckMate 9ER, the phase 3 pivotal study evaluating the combination of cabozantinib and nivolumab versus sunitinib in patients with previously untreated advanced or metastatic RCC, completed enrollment. The trial randomized approximately 650 patients globally. CheckMate 9ER is sponsored by Bristol-Myers Squibb Company (BMS) and co-funded by Exelixis and Exelixis' partners, Ipsen and Takeda. Results from the trial are expected in early 2020.

Initiation of COSMIC-313, a 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. In May, Exelixis announced the initiation of COSMIC-313, a multicenter, randomized, double-blinded, controlled phase 3 pivotal trial that is designed to enroll 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 is being conducted in collaboration with BMS, which is providing nivolumab and ipilimumab for use in this trial.

Expansion to Clinical Research Protocol for Phase 1b COSMIC-021 Trial. In July, Exelixis announced an amendment to the protocol for COSMIC-021, the phase 1b trial of cabozantinib in combination with TECENTRIQ® (atezolizumab), an anti-PDL1 antibody discovered and developed by Genentech, Inc. (a member of the Roche Group), in patients with locally advanced or metastatic solid tumors. Based on preliminary encouraging activity and safety data, the original cohorts for immune checkpoint inhibitor-refractory non-small cell lung cancer and metastatic castration-resistant prostate cancer (CRPC) are being expanded to 80 patients each. In addition, four new cohorts - two expansion and two exploratory - in metastatic CRPC settings are being added to the trial. There are currently a total of 20 expansion cohorts and four exploratory cohorts in the trial, which now has a targeted enrollment of up to 1,732 patients. The primary goal of COSMIC-021 remains to determine the objective response rate in each cohort.

Corporate Highlights

Daiichi Sankyo Launches MINNEBRO Tablets for the Treatment of Hypertension in Japan. In May, Exelixis announced that its partner Daiichi Sankyo launched MINNEBRO tablets as a treatment for patients with hypertension in Japan. 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 recognized and received a $20.0 million milestone payment from Daiichi Sankyo in June

2019 for 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.

Exelixis and Iconic Enter into Exclusive Option and License Agreement for Novel Antibody-Drug Conjugate (ADC) Program. In May, Exelixis announced an exclusive option and license agreement with Iconic, a private biopharmaceutical company focused on cancer and retinal disease, to advance an innovative next-generation ADC program for cancer. Under the terms of the agreement, Exelixis will gain an exclusive option to license ICON-2, Iconic's lead oncology ADC program targeting Tissue Factor in solid tumors, in exchange for an upfront option payment of $7.5 million and a commitment for preclinical development funding. During the second quarter of 2019, Exelixis accrued $5.1 million for the preclinical development funding commitment.

Presence at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting. In June, data from clinical trials of cabozantinib were featured in nine presentations at the ASCO Annual Meeting in Chicago. Cobimetinib was the subject of two additional presentations.

Exelixis and Aurigene Discovery Technologies Limited (Aurigene) Enter into Exclusive Option and License Agreement to Discover and Develop Novel Therapies for Cancer. In July, Exelixis announced an exclusive option and license agreement with Aurigene, a biotechnology company based in India focused on oncology and inflammatory disorders, to in-license up to six oncology programs from Aurigene. Under the terms of the agreement, Exelixis will make an upfront payment of $10.0 million for exclusive options to license three preexisting programs. In addition, Exelixis and Aurigene will initiate three Aurigene-led drug discovery programs on mutually agreed upon targets for additional upfront payments of $2.5 million per program. Exelixis will also contribute research funding to Aurigene for discovery and preclinical development work on all six programs. If Exelixis exercises an option, it would assume responsibility for all further development, commercialization and global manufacturing of that program, and Aurigene would become eligible for potential development, regulatory and commercialization milestone payments, as well as royalties on potential sales. Under the terms of the agreement, Aurigene retains limited development and commercial rights for India and Russia.

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

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second 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, July 31, 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 6687332 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on August 2, 2019. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 6687332. 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 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' intention to advance the business with a focus on sustainable long-term growth through commercial execution, thoughtful research and development investments, and financial discipline; Exelixis' updated 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' eligibility for additional development, regulatory and first-sale milestone payments, as well as royalties on sales under its collaboration with Takeda; Exelixis' expectation of results in early 2020 from CheckMate 9ER; Exelixis' eligibility for additional commercialization milestone payments, as well as low double-digit royalties on sales of MINNEBRO; Exelixis' financial and other obligations under each of its option and license agreements with Iconic and Aurigene; 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 1, 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 July 31, 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	$ 193,675	$ 145,836	$ 373,256	$ 280,108
Collaboration revenues	46,600	40,272	82,506	119,719
Total revenues	240,275	186,108	455,762	399,827
Operating expenses:				
Cost of goods sold	7,539	5,997	15,040	11,636
Research and development	81,932	42,488	145,221	80,245
Selling, general and administrative	58,815	51,853	118,953	105,869
Total operating expenses	148,286	100,338	279,214	197,750
Income from operations	91,989	85,770	176,548	202,077
Other income (expense), net:				
Interest income	6,975	2,697	13,062	4,592
Other, net	803	(72)	828	97
Total other income (expense), net	7,778	2,625	13,890	4,689
Income before income taxes	99,767	88,395	190,438	206,766
Provision for income taxes	(20,725)	(901)	(35,621)	(3,415)
Net income	$ 79,042	$ 87,494	$ 154,817	$ 203,351
Net income per share, basic	$ 0.26	$ 0.29	$ 0.51	$ 0.68
Net income per share, diluted	$ 0.25	$ 0.28	$ 0.49	$ 0.65
Shares used in computing net income per share, basic	302,188	297,336	301,365	296,874
Shares used in computing net income per share, diluted	314,911	312,241	314,786	313,024

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

	June 30, 2019	December 31, 2018[1]
Cash and investments [2]	$ 1,161,002	$ 851,621
Working capital	$ 846,451	$ 791,544
Total assets	$ 1,643,098	$ 1,422,286
Total stockholders' equity	$ 1,488,632	$ 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 June 30, 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
GAAP net income	$ 79,042	$ 87,494	$ 154,817	$ 203,351
Adjustments:				
Stock-based compensation - research and development expenses	5,138	2,900	9,444	5,933
Stock-based compensation - selling, general and administrative expenses	9,941	6,383	18,164	12,655
Income tax effect of the above adjustments	(3,385)	(180)	(6,194)	(380)
Non-GAAP net income	$ 90,736	$ 96,597	$ 176,231	$ 221,559
GAAP net income per share, basic	$ 0.26	$ 0.29	$ 0.51	$ 0.68
GAAP net income per share, diluted	$ 0.25	$ 0.28	$ 0.49	$ 0.65
Non-GAAP net income per share, basic	$ 0.30	$ 0.32	$ 0.58	$ 0.75
Non-GAAP net income per share, diluted	$ 0.29	$ 0.31	$ 0.56	$ 0.71
Shares used in computing net income per share, basic	302,188	297,336	301,365	296,874
Shares used in computing net income per share, diluted	314,911	312,241	314,786	313,024

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