Exelixis Announces Third Quarter 2019 Financial Results and Provides Corporate Update

October 30, 2019

- Total Revenue of $271.7 Million, Cabozantinib Franchise Revenue of $191.8 Million -
- GAAP Diluted EPS of $0.31, Non-GAAP Diluted EPS of $0.34 -
- Conference Call and Webcast Today at 5:00 PM Eastern Time -

ALAMEDA, Calif.--(BUSINESS WIRE)--Oct. 30, 2019-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third quarter of 2019 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

"In the third quarter of 2019, we made strong progress across all components of our business, highlighted in particular by our clinical and business development activities. Importantly, for the first time, global cabozantinib franchise net revenue exceeded $1 billion over four consecutive quarters," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Based on encouraging early clinical data, we expanded the COSMIC-021 study, our phase 1b trial of cabozantinib and atezolizumab across multiple tumor types, and we entered into a collaboration with Aurigene, our second in-licensing agreement of 2019, to develop novel therapies for cancer."

Dr. Morrissey continued: "As we close out Exelixis' 25 th year, our focus remains on continued execution across the organization, all towards building momentum for key milestones anticipated in 2020, including clinical results early in the year from the phase 3 pivotal CheckMate 9ER study being conducted in collaboration with Bristol-Myers Squibb, additional clinical data emerging from COSMIC-021 and initiating new pivotal trials which aim to expand the cabozantinib franchise opportunity. Furthermore, our continued positive cash flow enables us to drive toward building sustainable long-term growth through our internal discovery activities and targeted business development opportunities with the potential to expand the breadth and depth of our pipeline."

Third Quarter 2019 Financial Results

Total revenues for the quarter ended September 30, 2019 were $271.7 million, compared to $225.4 million for the comparable period in 2018.

Total revenues included net product revenues of $191.8 million for the quarter ended September 30, 2019, compared to $162.9 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.

Total revenues for the quarter ended September 30, 2019 also include collaboration revenues of $79.9 million, compared to $62.5 million for the comparable period in 2018. The increase in collaboration revenues was primarily the result of the recognition of a $50.0 million milestone from Exelixis' collaboration with Ipsen Pharma SAS (Ipsen) for the achievement of $250.0 million of net sales of cabozantinib in its territories over four consecutive fiscal quarters. In the comparable period in 2018, Exelixis recognized $42.6 million in milestone revenues from Ipsen.

Research and development expenses for the quarter ended September 30, 2019 were $97.3 million, compared to $44.7 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 and personnel expenses. 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, option and license agreement Exelixis entered into with Aurigene Discovery Technologies Limited (Aurigene) in July 2019. The increase in personnel expenses was primarily due to increases in headcount to support Exelixis' expanded discovery and development efforts.

Selling, general and administrative expenses for the quarter ended September 30, 2019 were $51.3 million, compared to $48.1 million for the comparable period in 2018. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses and stock-based compensation partially offset by a decrease in corporate giving. The increase in personnel expenses was primarily due to increases in administrative headcount to support Exelixis' commercial and research and development organizations. The increase in stock-based compensation was primarily due to increases in headcount, as well as the expense recognition for restricted stock units that were granted in September 2018 that either have vested or will vest upon the achievement of specific performance targets.

Provision for income taxes for the quarter ended September 30, 2019 was $25.2 million and Exelixis' effective tax rate was 20.5%, compared to $2.3 million and 1.8%, respectively, for the comparable period in 2018. The provision for income taxes relating to Exelixis' pre-tax income for the three months ended September 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 September 30, 2019 was $97.5 million, or $0.32 per share, basic and $0.31 per share, diluted, compared to GAAP net income of $126.6 million, or $0.42 per share, basic and $0.41 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 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 September 30, 2019 was $107.6 million, or $0.35 per share, basic and $0.34 per share, diluted, compared to non-GAAP net income of $136.2 million, or $0.46 per share, basic and $0.44 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 approximately $1.2 billion at September 30, 2019, compared to approximately $852 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 approximately $350 million given the impact of the recent business development activities and include non-cash expenses related to stock-based compensation of approximately $20 million. Selling, general and administrative expenses are expected to be approximately $240 million and include non-cash expenses related to stock-based compensation of approximately $40 million. Guidance for the effective tax rate in 2019 is between 21% and 23%.

Cabozantinib Highlights

Continued Growth in Cabozantinib Franchise Net Revenues and Royalties. Net product revenues generated by the cabozantinib franchise in the U.S. were $191.8 million during the third quarter of 2019, an increase of 17.7% year-over-year, with net product revenues of $187.4 million for CABOMETYX and $4.4 million for COMETRIQ® (cabozantinib). Based upon Exelixis' partner Ipsen's cabozantinib-related revenues in the third quarter of 2019, Exelixis earned $16.4 million in royalty revenues at the 22% royalty rate. Cabozantinib continues to expand its global footprint, where it is currently approved and commercially available in 49 and 34 countries, respectively. For the first time, global cabozantinib franchise net revenue exceeded $1 billion over four consecutive quarters.

$50.0 Million Milestone Earned from Ipsen Triggered by Growth of Cabozantinib Ex-U.S. Sales. In the third quarter of 2019, Ipsen reported cabozantinib net sales of approximately $73 million in its territories using the contractual exchange rate, resulting in the achievement of $250.0 million of net sales of cabozantinib cumulatively over four consecutive fiscal quarters, and triggering a $50.0 million milestone to Exelixis. The milestone was earned and recognized by Exelixis in the third quarter of 2019, with the receipt of the cash payment anticipated in the fourth quarter of 2019.

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 immunotherapy-refractory non-small cell lung cancer and metastatic castration-resistant prostate cancer (CRPC) cohorts were expanded to 80 patients each. In addition, four new cohorts - two expansion and two exploratory - in metastatic CRPC settings were added to the trial. There are now 24 total cohorts, with 20 cohorts evaluating the combination of cabozantinib and atezolizumab and four cohorts evaluating cabozantinib or atezolizumab as single-agent therapies, and the trial 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.

Health Canada Approves CABOMETYX for First-Line Treatment of Adults with Advanced RCC. In October, Ipsen announced Health Canada's approval of CABOMETYX for the first-line treatment of adults with advanced RCC. Under the collaboration agreement with Ipsen, Exelixis is eligible to receive a $3.0 million milestone for the Health Canada approval, which will be recognized as revenue in the fourth quarter of 2019. CABOMETYX was originally approved in Canada in September 2018 for the treatment of adults with advanced RCC who have received prior vascular endothelial growth factor targeted therapy.

Corporate Updates

Exelixis and Aurigene Enter into Exclusive Collaboration, Option and License Agreement to Discover and Develop Novel Therapies for Cancer. In July, Exelixis announced an exclusive collaboration, option and license agreement with Aurigene, an India-based biotechnology company focused on oncology and inflammatory disorders, to in-license as many as six programs. Under the terms of the agreement, Exelixis made an upfront payment of $10.0 million for exclusive options to license three preexisting programs from Aurigene. In addition, Exelixis and Aurigene selected three additional Aurigene-led drug discovery programs on mutually agreed upon targets, in exchange for additional option payments totaling $7.5 million. Exelixis will also contribute research funding to facilitate discovery and preclinical development work on all six programs.

Exelixis and Invenra, Inc. (Invenra) Expand Collaboration Focused on the Discovery and Development of Multispecific Antibodies for the Treatment of Cancer. In October, Exelixis expanded its collaboration with Invenra to include the development of novel binders against six additional targets. Under the terms of the expanded collaboration agreement, Exelixis will have the option to use these binders to generate multispecific antibodies based on Invenra's B-Body™ technology platform, or with other platforms and formats, at Exelixis' option.

Exelixis Files Lawsuit to Enforce Its Intellectual Property Rights for CABOMETYX against Abbreviated New Drug Application (ANDA) Filer. In October, Exelixis filed a patent infringement lawsuit against MSN Pharmaceuticals, Inc. (MSN), following receipt of a Paragraph IV certification notice letter from MSN that it had filed an ANDA with the FDA requesting approval to market a generic version of CABOMETYX tablets, following

expiration of the CABOMETYX composition of matter patent, U.S. Patent No. 7,579,473, which expires on August 14, 2026. Exelixis is seeking, among other relief, an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of U.S. Patent No. 8,877,776 on October 8, 2030 and equitable relief enjoining MSN from infringing this patent.

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 September 27, 2019, December 28, 2018 and September 28, 2018 are indicated as being as of and for the periods ended September 30, 2019, December 31, 2018 and September 30, 2018, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the third 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, October 30, 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 5489464 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on November 1, 2019. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 5489464. 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 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: Key milestones anticipated in 2020, including clinical results early in the year from CheckMate 9ER, data from COSMIC-021 and initiating new pivotal trials which aim to expand the cabozantinib franchise opportunity; Exelixis' belief that its continued positive cash flow enables the company to drive toward sustainable long-term growth through internal discovery activities and targeted business development opportunities with the potential to expand the breadth and depth of its pipeline; 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; the anticipated timing for receipt of milestone payments from Ipsen; and Exelixis' financial and other obligations under each of its collaboration agreements with Aurigene and Invenra. 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 July 31, 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 October 30, 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	$ 191,768	$ 162,946	$ 565,024	$ 443,054
Collaboration revenues	79,935	62,451	162,441	182,170
Total revenues	271,703	225,397	727,465	625,224
Operating expenses:				
Cost of goods sold	7,537	7,360	22,577	18,996
Research and development	97,295	44,741	242,516	124,986
Selling, general and administrative	51,265	48,120	170,218	153,989
Total operating expenses	156,097	100,221	435,311	297,971
Income from operations	115,606	125,176	292,154	327,253
Other income (expense), net:				
Interest income	7,191	3,507	20,253	8,099
Other, net	(140)	271	688	368
Total other income (expense), net	7,051	3,778	20,941	8,467
Income before income taxes	122,657	128,954	313,095	335,720
Provision for income taxes	(25,205)	(2,324)	(60,826)	(5,739)
Net income	$ 97,452	$ 126,630	$ 252,269	$ 329,981
Net income per share, basic	$ 0.32	$ 0.42	$ 0.84	$ 1.11
Net income per share, diluted	$ 0.31	$ 0.41	$ 0.80	$ 1.05
Shares used in computing net income per share, basic	303,268	298,416	301,999	297,700
Shares used in computing net income per share, diluted	315,453	312,346	315,046	313,200

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

	September 30, 2019	December 31, 2018 [1]
Cash and investments [2]	$ 1,248,430	$ 851,621
Working capital	$ 831,043	$ 791,544
Total assets	$ 1,784,865	$ 1,422,286
Total stockholders' equity	$ 1,603,717	$ 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 $1.0 million as of September 30, 2019 and $1.1 million as of 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP net income	$ 97,452	$ 126,630	$ 252,269	$ 329,981
Adjustments:				
Stock-based compensation - research and development expenses	4,301	3,169	13,745	9,102
Stock-based compensation - selling, general and administrative expenses	8,838	6,573	27,002	19,228
Income tax effect of the above adjustments	(2,954)	(187)	(9,148)	(567)
Non-GAAP net income	$ 107,637	$ 136,185	$ 283,868	$ 357,744
GAAP net income per share, basic	$ 0.32	$ 0.42	$ 0.84	$ 1.11
GAAP net income per share, diluted	$ 0.31	$ 0.41	$ 0.80	$ 1.05
Non-GAAP net income per share, basic	$ 0.35	$ 0.46	$ 0.94	$ 1.20
Non-GAAP net income per share, diluted	$ 0.34	$ 0.44	$ 0.90	$ 1.14
Shares used in computing net income per share, basic	303,268	298,416	301,999	297,700
Shares used in computing net income per share, diluted	315,453	312,346	315,046	313,200

View source version on businesswire.com: https://www.businesswire.com/news/home/20191030005982/en/

Source: Exelixis, Inc.

Chris Senner
Chief Financial Officer
Exelixis, Inc.
650-837-7240
csenner@exelixis.com

Susan Hubbard
EVP, Public Affairs & Investor Relations
Exelixis, Inc.
650-837-8194
shubbard@exelixis.com