Exelixis Announces Third Quarter 2018 Financial Results and Provides Corporate Update

November 1, 2018

- Total Revenues of $225.4 million -

- Cabozantinib Franchise Net Product Revenues of $162.9 million -

- Net Income of $126.6 million, Diluted EPS of $0.41 -

- Conference Call and Webcast Today at 5:00 P.M. Eastern Daylight Time -

ALAMEDA, Calif.--(BUSINESS WIRE)--Nov. 1, 2018-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third quarter of 2018 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 2018, we continued to grow our commercial business and make significant clinical development and regulatory progress for our pipeline," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Cabozantinib franchise net product revenues during the quarter were $162.9 million, which represents a 12 percent increase compared to the second quarter of 2018. We also initiated the next wave of cabozantinib pivotal trials with the announcement of the COSMIC-311 study in differentiated thyroid cancer and expect additional pivotal trials launching later this year and into 2019. This will include studies evaluating cabozantinib in combination with leading immunotherapies, an approach supported by encouraging clinical data, including phase 1b dose escalation results of cabozantinib plus atezolizumab in advanced renal cell carcinoma presented at the 2018 European Society for Medical Oncology Congress last month."

Dr. Morrissey continued: "Our team's hard work provides strong momentum as we close out the year and move into 2019. In particular, we look forward to the U.S. Food and Drug Administration's upcoming decision on our supplemental New Drug Application for CABOMETYX ® in previously-treated advanced hepatocellular carcinoma, which has a January 14, 2019 action date, and for which we are fully launch ready. We are also pleased with Ipsen's regulatory progress, including gaining a positive opinion in the European Union for previously-treated hepatocellular carcinoma, and Canadian regulatory approval for advanced renal cell carcinoma. Each of these milestones has the potential to support broadened access to CABOMETYX in key regions, and underscores our commitment to making Exelixis-discovered medicines globally available to cancer patients in need."

Third Quarter 2018 Financial Results

Total revenues for the quarter ended September 30, 2018 were $225.4 million, compared to $152.5 million for the comparable period in 2017.

Total revenues include net product revenues of $162.9 million for the quarter ended September 30, 2018, compared to $96.4 million for the comparable period in 2017, representing a 69 percent increase year-over-year. The increase in net product revenues reflects the continued growth of CABOMETYX in the U.S. for the treatment of advanced renal cell carcinoma (RCC).

Total revenues also include collaboration revenues of $62.5 million for the quarter ended September 30, 2018 compared to $56.1 million for the comparable period in 2017. Collaboration revenues for the quarter ended September 30, 2018 included the recognition of milestone revenue of $36.9 million and $5.0 million from our collaboration with Ipsen Pharma SAS (Ipsen) for the anticipated approval of CABOMETYX for previously-treated hepatocellular carcinoma (HCC) in the European Union and the approval by Health Canada of CABOMETYX for previously-treated RCC, respectively. Collaboration revenues also included $11.7 million in royalties earned from Ipsen and Genentech and $6.9 million in development cost reimbursements under our collaboration agreements with Ipsen and Takeda Pharmaceutical Company Ltd. Collaboration revenues for the quarter ended September 30, 2017 included two milestones totaling $45.0 million from our collaboration with Ipsen.

Research and development expenses for the quarter ended September 30, 2018 were $44.7 million, compared to $28.5 million for the comparable period in 2017. The increase in research and development expenses was primarily related to increases in clinical trial costs and personnel expenses. The increase in clinical trial costs was primarily due to increased costs associated with: CheckMate 9ER, a phase 3 pivotal trial of cabozantinib plus immunotherapy in patients with previously-untreated RCC that is being conducted with Bristol-Myers Squibb Company; COSMIC-311, a phase 3 pivotal trial of cabozantinib in patients with radioiodine-refractory differentiated thyroid cancer (DTC) who have progressed after prior VEGFR-targeted therapy; and the preparation for further pivotal phase 3 trials that are expected to be initiated in the coming months. The increase in personnel expenses was primarily due to increases in headcount to support our expanded development and discovery efforts.

Selling, general and administrative expenses for the quarter ended September 30, 2018 were $48.1 million, compared to $38.1 million for the comparable period in 2017. The increase in selling, general and administrative expenses was primarily related to increases in personnel expenses and stock-based compensation. The increase in personnel expenses was primarily due to increases in general and administrative headcount to support the company's commercial and research and development organizations. The increase in stock-based compensation was primarily due to the increase in headcount.

Net income for the quarter ended September 30, 2018 was $126.6 million, or $0.42 per share, basic and $0.41 per share, diluted, compared to $81.4 million, or $0.28 per share, basic and $0.26 per share, diluted, for the comparable period in 2017. The increase in net income was primarily the result of increases in net product revenues and collaboration revenues, which was partially offset by the increases in research and development and selling, general and administrative expenses.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $750.3 million at September 30, 2018, as compared to $457.2 million at December 31, 2017.

2018 Financial Guidance

The company is updating its guidance that total costs and operating expenses for the full year will be between $410 million and $420 million. This guidance includes approximately $50 million of non-cash costs and expenses related primarily to stock-based compensation expense.

Cabozantinib Highlights

Strong Growth in Cabozantinib Franchise Net Revenues. Net product revenues generated by the cabozantinib franchise were $162.9 million during the third quarter of 2018, an increase of 69 percent year-over-year. During the third quarter of 2018, CABOMETYX generated $158.3 million in net product revenues and COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional $4.7 million in net product revenues.

CELESTIAL Phase 3 Pivotal Trial Results Published in *The New England Journal of Medicine* (*NEJM*). In July, Exelixis announced that *NEJM* published positive results from the CELESTIAL phase 3 pivotal trial of cabozantinib in patients with previously-treated advanced HCC. As previously announced and presented, the data demonstrate that cabozantinib provided a statistically significant and clinically meaningful improvement in overall survival versus placebo.

National Comprehensive Cancer Network (NCCN) Updates Clinical Practice Guidelines with New Recommendations for CABOMETYX. In September, the NCCN updated its Clinical Practice Guidelines to recommend CABOMETYX for the treatment of advanced RCC regardless of patient risk status (favorable-, intermediate-, and poor-risk). With the updates, CABOMETYX is the only tyrosine kinase inhibitor (TKI) indicated for the treatment of advanced RCC with NCCN-preferred status for intermediate- and poor-risk groups in the first-line setting, and the only TKI with preferred status for patients who have progressed on prior therapy.

In a separate update to the Clinical Practice Guidelines for Hepatobiliary Cancers, the NCCN also added cabozantinib as a Category 1 option for the treatment of patients with HCC (Child-Pugh Class A only) who have been previously treated with sorafenib. CABOMETYX is not a U.S. Food and Drug Administration (FDA) approved therapy for previously-treated advanced HCC. In May 2018, the FDA accepted Exelixis' supplemental New Drug Application (sNDA) for CABOMETYX in this disease setting, assigning a Prescription Drug User Fee Act date of January 14, 2019.

Health Canada Approves CABOMETYX for Previously-treated Advanced RCC. In September, Ipsen announced approval by Health Canada of CABOMETYX for the treatment of adults with advanced RCC who have received prior vascular endothelial growth factor-targeted therapy. Health Canada had granted CABOMETYX priority review status, which provided an accelerated review of Ipsen's new drug submission. Under the collaboration agreement with Ipsen, Exelixis is eligible to receive a $5.0 million milestone for the Health Canada approval, which was recognized as revenue in the third quarter of 2018.

Positive Committee for Medicinal Products for Human Use (CHMP) Opinion for CABOMETYX for Previously-treated HCC. In September, Ipsen announced that it received a positive opinion from the CHMP, the scientific committee of the European Medicines Agency, for CABOMETYX as a monotherapy for the treatment of HCC in adults who have been previously treated with sorafenib. The positive CHMP opinion will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union. The CHMP opinion was based on results from the CELESTIAL phase 3 pivotal trial. Under the collaboration agreement with Ipsen, Exelixis is eligible to receive a milestone payment of $40.0 million for the approval of CABOMETYX for previously-treated HCC, of which $36.9 million was recognized as revenue in the third quarter of 2018. Payment of the full $40.0 million is expected to be received within 70 days of an approval decision by the EC.

Initiation of COSMIC-311, Phase 3 Pivotal Trial of Cabozantinib in Patients with Radioiodine-refractory DTC Who Have Progressed After Prior VEGFR-Targeted Therapy. After the quarter ended, in October, Exelixis announced the initiation of COSMIC-311, a multicenter, randomized, double-blind, placebo-controlled phase 3 pivotal trial that aims to enroll approximately 300 patients at approximately 150 sites globally. The co-primary endpoints of the trial are progression-free survival and objective response rate. The American Cancer Society estimates that approximately 54,000 new cases of thyroid cancer will be diagnosed in the United States in 2018.[1] DTC accounts for approximately 90 percent of all thyroid cancers.[2]

Cabozantinib Data at the 2018 European Society for Medical Oncology (ESMO) Congress. After the quarter ended, in October, data from clinical trials of cabozantinib were featured in 13 presentations at the 2018 ESMO Congress in Munich, Germany. Notable results included further analyses from the CELESTIAL phase 3 pivotal trial, as well as single-agent and combination data for cabozantinib in a variety of tumor types and disease settings. One poster presentation highlighted results from the dose escalation stage of the phase 1b COSMIC-021 study of cabozantinib in combination with atezolizumab in previously-untreated advanced RCC, demonstrating that this therapy combination was well tolerated and showed encouraging anti-tumor activity in advanced RCC. A second poster presentation, reviewed during a discussion session, evaluated the effect of PD-L1 status on clinical outcomes with cabozantinib in advanced RCC in the CABOSUN and METEOR trials, and showed improved outcomes regardless of PD-L1 expression relative to sunitinib or everolimus, the respective comparator arms for each trial. Another poster presentation evaluated the activity of cabozantinib in patients with advanced RCC who had progressed on immune checkpoint inhibitor (ICI) therapy, finding that cabozantinib was active in patients previously-treated with ICIs, either alone or in combination with anti-VEGF or other therapies.

CABOMETYX as a Treatment for Advanced RCC Approved in Brazil and Taiwan. After the quarter ended, in October, Ipsen received approvals from both the Agência Nacional de Vigilância Sanitária in Brazil for CABOMETYX as a treatment for both previously-treated and previously-untreated advanced RCC and from the Taiwan Food and Drug Administration for CABOMETYX as a treatment for patients with advanced RCC who have received prior anti-angiogenic therapy.

Corporate Highlights

Inclusion on Standard & Poor's (S&P) MidCap 400 Index. On July 2, Exelixis began trading as a member of the S&P MidCap 400® classified under S&P's Global Industry Classification Standard Biotechnology Sub-Industry index. The index, which is distinct from the large-cap S&P 500®, measures the performance of profitable mid-sized companies, reflecting the distinctive risk and return characteristics of this market segment.

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 28, 2018, December 29, 2017 and September 29, 2017 are indicated as being as of

and for the periods ended September 30, 2018, December 31, 2017 and September 30, 2017, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the third quarter of 2018 and provide a general business update during a conference call beginning at 5:00 p.m. EDT / 2:00 p.m. PDT today, Thursday, November 1, 2018.

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 1043999 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT / 5:00 p.m. PDT on November 3, 2018. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 1043999. 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. We discovered our three commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib) and COTELLIC® (cobimetinib), and 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. In July 2018, Exelixis was added to the 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' expectation to launch additional pivotal clinical trials later in 2018 and in 2019, including studies evaluating cabozantinib in combination with leading immunotherapies; the impact of the FDA's upcoming decision on Exelixis' sNDA for CABOMETYX as a treatment option for patients with previously-treated advanced HCC; the potential of regulatory approval milestones outside the U.S. to support broadened access to CABOMETYX in key regions and Exelixis' commitment to making its discovered medicines globally available to cancer patients in need; Exelixis' guidance for 2018 total costs and operating expenses, including non-cash costs and expenses; eligibility for and the expected timing of receipt of milestone payments from Ipsen; 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 and COTELLIC and the availability of sufficient coverage and adequate reimbursement for these 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 and cobimetinib, 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' 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 or cobimetinib; 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 August 1, 2018, 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 November 1, 2018. 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.

[1] American Cancer Society, *Key Statistics for Thyroid Cancer,* https://www.cancer.org/cancer/thyroid-cancer/about/key-statistics.html, accessed October 2018.

[2] Cooper DS, et al, 2009, *Revised American Thyroid Association management guidelines for patients with thyroid nodules and differentiated thyroid cancer*, The American Thyroid Association (ATA) Guidelines Taskforce on Thyroid Nodules and Differentiated Thyroid Cancer, *Thyroid,* 19:1167-1214.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Net product revenues	$ 162,946	$ 96,416	$ 443,054	$ 253,297
Collaboration revenues	62,451	56,094	182,170	79,108
Total revenues	225,397	152,510	625,224	332,405
Operating expenses:				
Cost of goods sold	7,360	4,658	18,996	10,875
Research and development	44,741	28,543	124,986	79,967
Selling, general and administrative	48,120	38,129	153,989	113,084
Total operating expenses	100,221	71,330	297,971	203,926
Income from operations	125,176	81,180	327,253	128,479
Other income (expense), net:				
Interest income	3,507	1,133	8,099	3,497
Interest expense	(1)	—	(1)	(8,679)
Other, net	272	2,275	369	(3,638)
Total other income (expense), net	3,778	3,408	8,467	(8,820)
Income before income taxes	128,954	84,588	335,720	119,659
Provision for income taxes	2,324	3,206	5,739	3,921
Net income	$ 126,630	$ 81,382	$ 329,981	$ 115,738
Net income per share, basic	$ 0.42	$ 0.28	$ 1.11	$ 0.39
Net income per share, diluted	$ 0.41	$ 0.26	$ 1.05	$ 0.37
Shares used in computing net income per share, basic	298,416	294,269	297,700	292,776
Shares used in computing net income per share, diluted	312,346	312,940	313,200	311,555

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

	September 30, 2018	December 31, 2017 [1]
Cash and investments [2]	$ 750,320	$ 457,176
Working capital	$ 696,056	$ 369,704
Total assets	$ 1,024,366	$ 655,294
Total stockholders' equity	$ 915,966	$ 284,961

(1) Derived from the audited consolidated financial statements.
(2) Cash and investments include cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments. Short- and long-term restricted cash and investments totaled $1.6 million as of September 30, 2018 and $5.2 million as of December 31, 2017.

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Source: Exelixis, Inc.

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