Exelixis Announces Second Quarter and Year to Date 2016 Financial Results and Provides Corporate Update

August 3, 2016

- Launch of CABOMETYX Results in Cabozantinib Franchise Sales of $31.6 Million -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 3, 2016-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the second quarter of 2016 and provided an update on progress toward delivering upon its key 2016 corporate objectives, as well as commercial and clinical development milestones.

Exelixis is focused on executing the U.S. launch of CABOMETYX™ (cabozantinib) tablets as a treatment for patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. The first prescriptions for CABOMETYX were filled within three days of approval by the U.S. FDA on April 25. CABOMETYX generated $17.6 million in net product revenue during the remaining nine weeks of the second quarter of 2016. Net product revenues for the second quarter of 2016, including sales of COMETRIQ® (cabozantinib) capsules, were $31.6 million.

"The Exelixis team has worked tirelessly to prepare for and execute on the U.S. launch of CABOMETYX in order to bring this important new therapeutic option for advanced kidney cancer to prescribing clinicians and the patients they serve," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "We are encouraged by the initial uptake in May and June and are steadfast in our efforts to support the launch by educating the treatment community on the data in the CABOMETYX label, which differentiate this medicine from others available for patients with previously-treated advanced renal cell carcinoma."

Cabozantinib Highlights

CABOMETYX Approved by U.S. FDA. On April 25, 2016, the U.S. FDA approved CABOMETYX for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy. CABOMETYX is the first therapy to demonstrate robust and clinically meaningful improvements in all three key efficacy parameters - overall survival (OS), progression-free survival (PFS) and objective response rate (ORR) - in a phase 3 trial (METEOR) of patients with advanced RCC. Approximately 17,000 patients with advanced RCC in the U.S. and 37,000 globally require second-line or later treatment.[1]

Positive Top-Line Results from CABOSUN Randomized Phase 2 Trial. On May 23, 2016, Exelixis announced that CABOSUN, the independent randomized phase 2 trial of cabozantinib in patients with previously untreated advanced RCC, met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in PFS compared with sunitinib in patients with advanced intermediate- or poor-risk RCC. CABOSUN is being conducted by The Alliance for Clinical Trials in Oncology as part of Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP). Presentation of the CABOSUN results is planned for an upcoming medical meeting. Exelixis is discussing the results with regulatory authorities and evaluating potential next steps in the development and submission strategy for cabozantinib as a first-line treatment for patients with advanced RCC.

European CHMP Adopts Positive Opinion for Cabozantinib for the Treatment of Advanced RCC. On July 22, 2016, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion of the Marketing Authorization Application (MAA) for cabozantinib for the treatment of adult patients with advanced RCC who have received at least one prior VEGF receptor tyrosine kinase inhibitor therapy. The CHMP's positive opinion will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union. Exelixis and Ipsen, its partner for the development and commercialization of cabozantinib outside of the United States, Canada and Japan, anticipate a decision from the EC before the end of this year.

CELESTIAL Second-line Hepatocellular Carcinoma (HCC) Data Anticipated in 2017. Enrollment continues for CELESTIAL, the phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC who have previously been treated with sorafenib. Initiated in September 2013, the trial is designed to enroll 760 patients at approximately 200 sites. Patients are being randomized 2:1 to receive 60 mg of cabozantinib daily or placebo. The primary endpoint for CELESTIAL is OS, and the secondary endpoints include PFS and ORR. Exelixis anticipates results from this trial in 2017. New treatment options are needed for HCC patients who progress following sorafenib, the current standard of care.

Other Cabozantinib Development Program Updates. While Exelixis pursues cabozantinib's late-stage development in advanced RCC and advanced HCC, earlier-stage investigation of the compound continues through the company's collaboration with the NCI-CTEP, and its ongoing Investigator-Sponsored Trial (IST) program. Through these two programs, there are more than 45 ongoing or planned studies including trials in advanced RCC, bladder cancer, colorectal cancer (CRC), non-small cell lung cancer, and endometrial cancer. Data from several studies, including CABOSUN and a phase 1b study evaluating the combination of cabozantinib with nivolumab or nivolumab and ipilimumab, are expected to be presented in the second half of 2016.

Cobimetinib Highlights

Initiation of COTEZO Phase 3 Pivotal Trial in Advanced CRC. In June 2016, Exelixis' partner Genentech (a member of the Roche Group)

announced the initiation of COTEZO, the phase 3 pivotal trial of the combination of cobimetinib, the Exelixis-discovered MEK inhibitor, and atezolizumab, an anti-PD-L1 antibody, in unresectable locally advanced or metastatic CRC. COTEZO is designed to enroll 360 patients who have received at least two prior chemotherapies in the metastatic disease setting, and the primary endpoint of the trial is OS. The decision to start COTEZO was informed by results from the ongoing phase 1b trial of the combination in advanced solid tumors, and results from CRC patients enrolled in this trial were presented during an oral presentation at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2016.

Additional Regulatory Approvals for COTELLIC®. In April and May 2016, Australia's Therapeutic Goods Administration and Brazil's ANVISA, respectively, approved COTELLIC for use in combination with Zelboraf for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

Corporate Highlights

Cabozantinib, Cobimetinib and XL888 Data Presentations at ASCO 2016. Exelixis-discovered compounds were the subject of 18 presentations at the meeting, including an oral presentation of the OS results from the METEOR study in advanced RCC, as well as a poster presentation from the same trial on outcomes based on prior therapy or presence of bone metastases. Additional presentations highlighted results from early and mid-stage trials of cabozantinib in other disease settings, including metastatic CRC, endometrial cancer and metastatic urothelial carcinomas. Cobimetinib data included updates on combination trials of the compound in metastatic melanoma, triple-negative breast cancer, and CRC. On Sunday, June 5, 2016, Exelixis hosted an investor/analyst briefing at the meeting. The event featured a Q&A session with METEOR's principal investigator, Dr. Toni Choueiri of the Dana-Farber Cancer Institute and Dr. Thomas Hutson of Baylor University Medical Center. An archive of the briefing is available on the Event Calendar page under Investors & Media at www.exelixis.com.

Dr. Morrissey continued, "Our clinical development and regulatory efforts were highly productive during the second quarter. The positive top-line results for the CABOSUN trial sponsored by our collaborators at NCI-CTEP suggest that cabozantinib has potential as a treatment for previously-untreated patients with advanced RCC, and we are discussing potential next steps with regulators. The second half of 2016 will be eventful for Exelixis, as we will continue to advance the U.S. launch of CABOMETYX, while awaiting with our partner Ipsen the EC's decision in the European Union. We look forward to the presentation of the CABOSUN data later this year and ongoing enrollment of patients in CELESTIAL with potential results in 2017. And finally, we continue to monitor the progress of our partner, Genentech, with the cobimetinib development program, including COTEZO, the recently initiated second pivotal trial of this Exelixis-discovered compound in combination with atezolizumab in refractory CRC."

2016 Financial Guidance

The company is refining its guidance that operating expenses for the full year 2016 will be between $250 million and $270 million, including approximately $30 million of non-cash items primarily related to stock-based compensation expense.

Second Quarter 2016 Financial Results

Net revenues for the quarter ended June 30, 2016 were $36.3 million, compared to $8.0 million for the comparable period in 2015. Net revenues for the second quarter of 2016 include $31.6 million of net product revenue compared to $8.0 million for the comparable period in 2015. The increase in net product revenues for the three months ended June 30, 2016, as compared to the same period in 2015, reflects the impact of the commercial launch of CABOMETYX in late April 2016, as well as an increase in COMETRIQ revenues. Net product revenues for CABOMETYX and COMETRIQ were $17.6 million and $14.0 million respectively. Product revenues for CABOMETYX and COMETRIQ are both recognized using the "sell-in" method of revenue recognition. Product revenues during the quarter ended June 30, 2016 were impacted by the build of channel inventory related to the initial launch period for CABOMETYX. Net revenues also includes $3.6 million of license revenues recognized from the $200 million upfront payment we received in February 2016 from Ipsen under our collaboration and license agreement and $1.0 million of royalties on ex-U.S. net sales of COTELLIC. There was no such royalty or license revenue during the comparable period in 2015.

Research and development expenses for the quarter ended June 30, 2016 were $23.0 million, compared to $24.5 million for the comparable period in 2015. The decrease was primarily related to a decrease in clinical trial costs and the allocation of general corporate costs; those decreases were partially offset by increases in personnel related expenses resulting from an increase in headcount predominantly associated with the build-out of our Medical Science Liaison organization and an increase in consulting and outside services.

Selling, general and administrative expenses for the quarter ended June 30, 2016 were $35.8 million, compared to $12.8 million for the comparable period in 2015. The increase was primarily related to an increase in personnel related expenses resulting from an increase in headcount, predominantly connected to the expansion of our U.S. sales force and outside services expenses supporting the commercialization and launch of CABOMETYX.

Other income (expense), net for the quarter ended June 30, 2016 was a net expense of ($11.9) million compared to ($12.1) million for the comparable period in 2015. The net expense is comprised primarily of interest expense which includes $7.4 million of non-cash expense related to the accretion of the discounts on both the 4.25% Convertible Senior Subordinated Notes due 2019 and the company's indebtedness under our Secured Convertible Notes due 2018 held by entities associated with Deerfield for the quarter ended June 30, 2016, as compared to $7.2 million for the comparable period in 2015.

Net loss for the quarter ended June 30, 2016 was ($37.0) million, or ($0.16) per share, basic, compared to ($43.4) million, or ($0.22) per share, basic, for the comparable period in 2015. The decreased net loss for the quarter was primarily due to an increase in net revenues and a decrease in research and development expenses, which were partially offset by an increase in selling, general and administrative expenses.

Cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments totaled $384.0 million at June 30, 2016, which increased from $253.3 million at December 31, 2015 as a result of the $200.0 million upfront payment we received from Ipsen in connection with our February 29, 2016 licensing agreement.

Basis of Presentation

Exelixis 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 July 1, 2016, January 1, 2016 and July 3, 2015 are indicated as being as of and for the periods ended June 30, 2016, December 31, 2015 and June 30, 2015, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the second quarter of 2016 and provide a general business update during a conference call beginning at 5:00 p.m. EDT/2:00 p.m. PDT today, Wednesday, August 3, 2016.

To access the webcast link, log onto www.exelixis.com and proceed to the Event Calendar page under Investors & Media. 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 43700006 to join by phone.

A telephone replay will be available until 11:59 p.m. EDT on August 5, 2016. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 43700006. A webcast replay will also be archived on www.exelixis.com for one year.

About Exelixis

Exelixis, Inc. (Nasdaq: EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S.) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' focus on the U.S. launch for CABOMETYX as a treatment for patients with advanced RCC; the initial uptake of CABOMETYX and Exelixis' efforts to support the launch; the planned data presentation of the CABOSUN results at an upcoming medical meeting; the potential next steps in the development and submission strategy for cabozantinib as a first-line treatment for patients with advanced RCC; the review by the EC of the CHMP's positive opinion of the MAA for cabozantinib for the treatment of adult patients with advanced RCC and an anticipated decision from the EC before the end of this year; the status of enrollment progress for and the timing of anticipated top-line results from CELESTIAL; the continued late-stage development of cabozantinib pursued by Exelixis and earlier-stage investigation through Exelixis' collaboration with NCI-CTEP and its ongoing IST program; the expected timing of data results from CABOSUN and a phase 1b study evaluating the combination of cabozantinib with nivolumab or nivolumab and ipilimumab; the potential for cabozantinib as a treatment for previously-untreated patients with advanced RCC; an eventful second half of 2016 for Exelixis, including, the continued advancement of the U.S. launch of CABOMETYX, while awaiting the EC's decision in the European Union; Exelixis' continued monitoring of the progress of Genentech with the cobimetinib development program; Exelixis' refined guidance for 2016 operating expenses, including non-cash items; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "focused," "encouraged," "planned," "potential," "strategy," "will," "anticipate," "continues," "expected," "look forward," "guidance," "committed," or other similar expressions identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements 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 and COMETRIQ and the availability of coverage and reimbursement for CABOMETYX and COMETRIQ; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX or COMETRIQ; Exelixis' dependence on its relationship with Ipsen, including, the level of Ipsen's investment in the resources necessary to successfully commercialize cabozantinib in the territories where it is approved; the availability of data at the referenced times; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; the sufficiency of Exelixis' resources; costs associated with Exelixis' commercialization, research and development and other activities; Exelixis' dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; market competition; 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 4, 2016, 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 August 3, 2016. The forward-looking statements made in this press release speak only as of the date of this press release. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

1. Decision Resources Report: Renal Cell Carcinoma. October 2014 (internal data on file).

EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Net product revenues	$ 31,618	$ 7,992	$ 40,717	$ 17,380
Royalty, license and contract revenues	4,634	—	10,962	—
Total revenues	36,252	7,992	51,679	17,380
Operating expenses:				
Cost of goods sold	1,560	686	2,245	1,452
Research and development	22,984	24,506	51,910	46,788
Selling, general and administrative	35,823	12,789	70,680	22,320
Restructuring charge	1,021	1,291	1,115	860
Total operating expenses	61,388	39,272	125,950	71,420
Loss from operations	(25,136)	(31,280)	(74,271)	(54,040)
Other income (expense), net:				
Interest income and other, net	749	(123)	951	(130)
Interest expense	(12,628)	(11,959)	(25,042)	(24,362)
Total other income (expense), net	(11,879)	(12,082)	(24,091)	(24,492)
Net loss	$ (37,015)	$ (43,362)	$ (98,362)	$ (78,532)
Net loss per share, basic and diluted	$ (0.16)	$ (0.22)	$ (0.43)	$ (0.40)
Shares used in computing basic and diluted net loss per share	229,310	196,201	228,860	196,052

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	June 30, 2016 (unaudited)	**December 31, 2015** (1)
Cash and investments (2)	$ 383,996	$ 253,310
Working capital	$ 160,588	$ 126,414
Total assets	$ 477,136	$ 332,342
Total stockholders' deficit	$ (186,134)	$ (104,304)

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(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 $4.2 million and $2.7 million as of June 30, 2016 and December 31, 2015, respectively.

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