Exelixis Announces Fourth Quarter and Full Year 2015 Financial Results and Provides Corporate Update

February 29, 2016

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 29, 2016-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the fourth quarter and full year of 2015 and provided an overview of key 2016 corporate objectives and clinical development milestones.

Corporate Updates and Key Priorities for 2016

In 2016, Exelixis will continue to focus its development efforts and financial resources on the opportunities for cabozantinib in advanced renal cell carcinoma (RCC) and advanced hepatocellular carcinoma (HCC). With regulatory applications under review for advanced RCC in the United States and European Union (EU), Exelixis is actively preparing for the potential commercialization of cabozantinib as a treatment for patients with advanced RCC and will soon be launch-ready for this indication should a positive regulatory decision come in the United States.

At the same time, Exelixis is working with its partner Genentech, a member of the Roche Group, to co-promote COTELLIC™ (cobimetinib) in the United States. COTELLIC received U.S. approval in November 2015 as a treatment for patients with a BRAF V600E or V600K mutation-positive advanced melanoma, in combination with vemurafenib, also known as Zelboraf®. Exelixis is entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and currently shares equally in U.S. marketing and commercialization costs. COTELLIC is also approved in the EU, Canada and Switzerland, and Exelixis will receive low double-digit royalties based upon sales outside the United States.

Cabozantinib Highlights

METEOR Trial of Cabozantinib in Advanced Renal Cell Carcinoma Delivers Positive Overall Survival Results. On February 1, 2016, Exelixis announced that a second interim analysis for overall survival (OS), a secondary endpoint of the METEOR pivotal trial, showed a highly statistically significant and clinically meaningful increase in OS for patients randomized to cabozantinib as compared to everolimus. As a result, among all the existing agents evaluated in large pivotal trials in patients with advanced RCC, including nivolumab, cabozantinib is the first and only therapy to unequivocally demonstrate robust and statistically-significant improvements in all three key efficacy parameters of OS, progression-free survival (PFS), and objective response rate (ORR). Exelixis has shared these data with U.S. and EU regulators and intends to present the results at a major medical meeting this year.

Additional Positive Data Presented from Subgroup Analyses from METEOR Trial. In January 2016, Exelixis announced positive results from subgroup analyses of the METEOR trial. This analysis contributed important details to the previously-released results conducted at the time of primary endpoint, demonstrating that the PFS and ORR benefits derived from cabozantinib treatment were consistent across various prespecified and post-hoc analysis subgroups. Importantly, observed benefits were independent of the location and number of organ metastases, tumor burden, the type, duration and number of prior VEGF receptor TKI therapies, and prior PD-1/PD-L1 therapy. These data were presented on January 9, 2016 at the American Society of Clinical Oncology (ASCO) 2016 Genitourinary Cancers Symposium in San Francisco, CA.

U.S. Food and Drug Administration Accepts Filing for Advanced RCC, Grants Priority Review, and Assigns Action Date. In late January 2016, the U.S. Food and Drug Administration (FDA) deemed Exelixis' New Drug Application (NDA) for cabozantinib as a treatment for patients with advanced RCC who have received one prior therapy to be sufficiently complete to permit a substantial review. The FDA also granted Priority Review designation to the filing and assigned a Prescription Drug User Fee Act action date of June 22, 2016. The NDA was considered filed on February 20, 2016, sixty days following submission.

European Medicines Agency Validates Advanced RCC Regulatory Filing, Grants Accelerated Assessment. On January 28, 2016, Exelixis announced that the European Medicines Agency (EMA) has accepted for review the company's Marketing Authorization Application (MAA) for cabozantinib as a treatment for patients with advanced RCC who have received one prior therapy. With accelerated assessment, the MAA is eligible for a 150-day review, versus the standard 210 days (excluding clock stops when information is requested by the EMA).

Enrollment in CELESTIAL Continues; Data Anticipated in 2017. Exelixis continues to make progress in enrollment in CELESTIAL, a phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC who have previously been treated with sorafenib. The study was 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 continues to anticipate top-line results from CELESTIAL in 2017. At this time, there is no approved treatment for HCC patients who progress following sorafenib treatment, the current standard of care.

Broad Cabozantinib Development Program Continues to Expand through NCI and Independent Investigators. While Exelixis pursues cabozantinib's late-stage development in advanced RCC and advanced HCC, earlier-stage investigation continues through the company's collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program (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, non-small cell lung cancer, and endometrial cancer. Results are expected from the following clinical studies this year**:**

- CABOSUN, the randomized phase 2 trial comparing cabozantinib to sunitinib in the treatment of first-line intermediate or poor risk RCC patients, which completed enrollment in early 2015. CABOSUN is being conducted by The Alliance for

Clinical Trials in Oncology as part of Exelixis' collaboration with the NCI-CTEP;

- A phase 1b trial of cabozantinib plus nivolumab alone, or in combination with ipilimumab, in patients with genitourinary tumors, including bladder cancer and RCC; and
- A phase 2 trial evaluating single agent cabozantinib in recurrent endometrial cancer.

Cobimetinib Highlights

Regulatory Approvals for COTELLIC Granted in the United States, European Union and Canada. In November 2015, Exelixis announced that the FDA approved COTELLIC as a treatment for patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

Also that month, Exelixis announced that the European Commission approved COTELLIC for use in combination with vemurafenib for the treatment of adult patients in the EU with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. Additionally, in February 2016, Health Canada approved COTELLIC in combination with vemurafenib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

Positive Overall Survival Data for COTELLIC in Combination with Vemurafenib in Advanced Melanoma. In October 2015, Exelixis announced that the phase 3 coBRIM trial of COTELLIC in combination with vemurafenib met its secondary endpoint of demonstrating a statistically significant and clinically meaningful increase in OS for patients with unresectable locally advanced or metastatic melanoma carrying the BRAF V600E or V600K mutation. These data were the subject of a presentation at the Society for Melanoma Research 2015 Congress.

2016 Financial Guidance

The Company anticipates that operating expenses for the full year 2016 will be between $240 million and $270 million, including approximately $30 million of non-cash items related to stock-based compensation expense.

"Exelixis began 2016 with significant momentum as a result of the major milestones that occurred during and shortly after the fourth quarter," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Most notably, we now have a more complete picture of cabozantinib's clinical activity and potential in advanced renal cell carcinoma, a patient population greatly in need of new treatment options. With the announcement of positive overall survival data earlier this month, cabozantinib is now the only therapy to demonstrate in a phase 3 trial statistically significant improvements as compared to an active comparator, everolimus, in the three key efficacy parameters of overall survival, progression-free survival, and objective response rate in previously-treated patients with advanced renal cell carcinoma. As regulators continue to review our submitted applications, we are on track to be commercially ready in the United States by April 1, should we receive a regulatory decision in advance of the June 22 PDUFA date. And finally, with this afternoon's announcement, in Ipsen we now have the ideal partner to maximize the potential for cabozantinib to have a positive impact on the treatment of cancer on a global basis."

"Our second Exelixis-discovered compound, cobimetinib, also saw numerous milestones in the fourth quarter, including regulatory approval in the United States and European Union, as well as the presentation of overall survival results in advanced melanoma. Approval in Canada was also obtained this month. The collective progress in advancing both of these compounds sets the company up for an impactful year, and we remain grateful for the support of our stakeholders as we continue to make progress in our mission to meaningfully improve the care and outcomes for people with cancer."

Fourth Quarter and Full Year 2015 Financial Results

Net revenues for the quarter ended December 31, 2015 were $9.9 million, and consisted almost entirely of net product revenue from the sale of COMETRIQ®. This is compared to $7.4 million for the comparable period in 2014.

For the year ended December 31, 2015, net revenues were $37.2 million, compared to $25.1 million for the comparable period in 2014. Net revenues for the year ended December 31, 2015 included $3.0 million of contract revenues for a milestone payment received from Merck in the third quarter of 2015 related to their worldwide license of our PI3K-delta program as well as the net product revenue related to the sale of COMETRIQ.

Research and development expenses for the quarter ended December 31, 2015 were $23.5 million, compared to $39.7 million for the comparable period in 2014; and for the year ended December 31, 2015 were $96.4 million, compared to $189.1 million for the comparable period in 2014. The decreases for both the quarter and year ended December 31, 2015 were primarily related to a net decrease in clinical trial costs related to COMET, the Company's phase 3 trial in metastatic castration-resistant prostate cancer and METEOR, the Company's phase 3 trial in advanced RCC, and to a lesser degree, decreases in personnel related expenses resulting from an overall reduction in headcount. Those decreases were partially offset by an increase in stock-based compensation expense for performance-based stock-options tied to the positive top-line data received from the METEOR trial and the anticipated acceptance of our NDA filing with the FDA.

Selling, general and administrative expenses for the quarter ended December 31, 2015 were $17.1 million, compared to $9.8 million for the comparable period in 2014; and for the year ended December 31, 2015 were $57.3 million, compared to $50.8 million for the comparable period in 2014. The increases for both the quarter and year ended December 31, 2015 were primarily related to stock-based compensation expense due to the vesting of performance-based stock-options as a result of the positive top-line data received from the METEOR trial and the anticipated acceptance of our NDA filing with the FDA and higher marking expenses. Our 2015 selling, general and administrative expenses include a portion of COTELLIC commercialization expenses allocated to the collaboration which are under discussion between Exelixis and Genentech.

The overall selling, general and administrative expenses increases were partially offset by a decrease in facilities costs and consulting and outside services. For the year ended December 31, 2015, there were also decreases in personnel related expenses resulting from an overall reduction in headcount and patent defense costs as compared to the comparable period in 2014.

Other income (expense), net for the quarter ended December 31, 2015 was a net expense of ($12.0) million compared to ($11.9) million for the comparable period in 2014. Other income (expense), net for the year ended December 31, 2015 was a net expense of ($48.3) million compared to $(44.3) million for the comparable period in 2014. The net expense is comprised primarily of interest expense which includes $7.1 million and $28.9

million, respectively 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 the Deerfield Notes for the quarter and year ended December 31, 2015, as compared to $7.7 million and $29.5 million for the comparable periods in 2014.

Net loss for the quarter ended December 31, 2015 was ($43.6) million, or ($0.19) per share, basic, compared to ($58.0) million, or ($0.30) per share, basic, for the comparable period in 2014. Net loss for the year ended December 31, 2015 was ($169.7) million, or ($0.81) per share, basic, compared to ($268.5) million, or $(1.38) per share, basic, for the comparable period in 2014. The decreases in net loss for both the quarter and year were primarily due to decreases in research and development expenses and an increase in net revenues, partially offset by an increase in selling, general and administrative expenses.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $253.3 million at December 31, 2015 compared to $242.8 million at December 31, 2014.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the fourth quarter and full year 2015, discuss today's announcement of the agreement with Ipsen, and provide a general business update during a conference call beginning at 5:00 p.m. EST/2:00 p.m. PST today, February 29, 2016. To listen to a live webcast of the conference call, visit the Event Calendar page under Investors & Media at www.exelixis.com. Alternatively, participants may dial (855) 793-2457 (domestic) or (631) 485-4921 (international) and provide the conference call passcode 20111969 to join by phone.

An archived replay of the webcast will be available on the Event Calendar page under Investors & Media at www.exelixis.com for one year. An audio-only phone replay will be available until 11:59 p.m. EST on March 2, 2016. Access numbers for the phone replay are: (855) 859-2056 (domestic) and (404) 537-3406 (international); the passcode is 20111969.

About Exelixis

Exelixis, Inc. is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its development and commercialization efforts primarily on cabozantinib, an internally discovered inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, COTELLIC™ (cobimetinib), a selective inhibitor of MEK, has been approved in Switzerland, the United States, the European Union, and Canada, and is being evaluated by Roche and Genentech (a member of the Roche Group) in a broad development program under a collaboration with Exelixis. For more information, please visit the company's website at www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the continued focus of Exelixis' development efforts and financial resources on the opportunities for cabozantinib in advanced RCC and advanced HCC; the status of Exelixis' preparations for a potential launch of cabozantinib in advanced RCC in the U.S., should a positive regulatory decision come in the U.S.; the financial terms of Exelixis' collaboration for cobimetinib with Genentech, including, the plan to share U.S. profits and losses for cobimetinib, and Exelixis' potential receipt of royalties on sales of cobimetinib products outside the U.S.; Exelixis' intent to present data from the second interim analysis of OS for METEOR at a medical conference later this year; the eligibility for an expedited review of Exelixis' MAA for cabozantinib in advanced RCC by the EMA; the status of enrollment progress for and the timing of anticipated top-line results from CELESTIAL; the expected timing of results for trials being conducted through Exelixis' collaboration with NCI-CTEP; Exelixis' anticipated operating expenses for 2016, including non-cash expenses and Exelixis' projections for cash interest expense; the impact of the collaboration with Ipsen on Exelixis' plan to maximize the potential for cabozantinib on a global basis; the expectation for Exelixis to have an impactful year; and the continued progress on Exelixis' mission to meaningfully improve the care and outcomes for people with cancer. Words such as "will," "continue," "focus," "opportunities," "potential," "should," "entitled," "intends," "eligible," "anticipate," "expected," "projects," 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 sufficiency of Exelixis' capital and other resources; Exelixis' ability to judge the proper size and level of experience of the commercialization teams required to support the launch of cabozantinib for advanced RCC in the U.S.; the clinical, therapeutic and commercial potential of cabozantinib and cobimetinib; Exelixis' dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; the availability of data at the referenced times; 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; 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; the risk that unanticipated developments could adversely affect the commercialization of COMETRIQ; the degree of market acceptance of COMETRIQ and the availability of coverage and reimbursement for COMETRIQ; 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 November 10, 2015, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' annual report on Form 10-K expected to be filed with the SEC on February 29, 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.

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014 (1)
Revenues:				
Net product revenues	$ 9,924	$ 7,353	$ 34,158	$ 25,111
License and contract revenues	14	—	3,014	—
Total revenues	9,938	7,353	37,172	25,111
Operating expenses:				
Cost of goods sold	1,023	684	3,895	2,043
Research and development	23,472	39,650	96,351	189,101
Selling, general and administrative	17,143	9,766	57,305	50,829
Restructuring charge	(100)	3,461	1,042	7,596
Total operating expenses	41,538	53,561	158,593	249,569
Loss from operations	(31,600)	(46,208)	(121,421)	(224,458)
Other income (expense), net:				
Interest income and other, net	266	555	412	4,341
Interest expense	(12,252)	(12,482)	(48,673)	(48,607)
Total other income (expense), net	(11,986)	(11,927)	(48,261)	(44,266)
Loss before income taxes	(43,586)	(58,135)	(169,682)	(268,724)
Income tax provision (benefit)	55	(182)	55	(182)
Net loss	$ (43,641)	$ (57,953)	$ (169,737)	$ (268,542)
Net loss per share, basic and diluted	$ (0.19)	$ (0.30)	$ (0.81)	$ (1.38)
Shares used in computing basic and diluted net loss per share	227,449	195,536	209,227	194,299

(1) Derived from the audited consolidated financial statements.

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

	December 31, 2015 (unaudited)	December 31, 2014 (1)
Cash and investments (2)	$ 253,310	$ 242,760
Working capital (deficit)	$ 126,414	$ (3,188)
Total assets	$ 332,342	$ 323,269
Total stockholders' deficit	$ (104,304)	$ (114,829)

(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. Long-term restricted cash and investments totaled $2.7 million as of December 31, 2015. Short- and long-term restricted cash and investments totaled $16.9 million as of December 31, 2014.

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Source: Exelixis, Inc.

Exelixis, Inc.
Chris Senner, 650-837-7240
Chief Financial Officer
csenner@exelixis.com
or
Exelixis, Inc.
Susan Hubbard, 650-837-8194
Investor Relations & Corporate Communications
shubbard@exelixis.com