Exelixis Announces First Quarter 2015 Financial Results and Provides Corporate Update

April 30, 2015

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 30, 2015-- Exelixis, Inc. (Nasdaq:EXEL) today reported financial results for the first quarter of 2015 and provided an update on progress toward its 2015 key corporate objectives and clinical development milestones.

Corporate Updates and Key Priorities for 2015

In 2015, Exelixis continues to focus its development efforts and financial resources on the opportunities for cabozantinib in metastatic renal cell carcinoma (mRCC) and advanced hepatocellular carcinoma (HCC), and to support its partner Genentech, a member of the Roche Group, as it prepares for the potential worldwide commercialization of cobimetinib, a second Exelixis-discovered compound.

mRCC Regulatory Progress and Anticipated Timing for Top-Line Results for METEOR Trial. In early April, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to cabozantinib as a treatment for patients with advanced RCC who have received one prior therapy. Fast Track designation confers important benefits, including the potential eligibility for Priority Review of a New Drug Application (NDA), if the relevant criteria as defined by FDA are met.

METEOR is the company's phase 3 pivotal trial of cabozantinib in mRCC. Enrollment was completed in November 2014, and the protocol specifies that the analysis of the primary endpoint, progression-free survival (PFS), will be conducted once 259 events have occurred among the first 375 patients enrolled. Exelixis previously stated that top-line results from METEOR were anticipated to be available in the second quarter of 2015; however, because the rate at which events associated with the primary endpoint of PFS are accumulating has slowed, the company now anticipates top-line results will be available at the end of the second quarter or early in the third quarter of this year.

Updates on National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP) and Investigator-Sponsored Trials (IST) of Cabozantinib. Exelixis' collaborators at NCI-CTEP and independent investigators are evaluating cabozantinib in tumor types beyond the company's phase 3 pivotal trials in mRCC and HCC. Following are a few program updates:

- The Alliance for Clinical Trials in Oncology (The Alliance) recently notified Exelixis that CABOSUN, the randomized phase 2 study of cabozantinib versus sunitinib in the first-line RCC setting, met its enrollment target of 150 patients determined to be intermediate or poor risk by the Heng criteria. The primary endpoint of CABOSUN is PFS. Given the historical PFS duration for sunitinib in similar patients in the first-line setting, Exelixis anticipates data from the trial in 2016. CABOSUN is being conducted by The Alliance as part of Exelixis' collaboration with the NCI-CTEP.
- Separately, the NCI-CTEP has received and notified Exelixis of top-line results from its randomized phase 2 trial (Study GOG-0186K) of cabozantinib versus paclitaxel (1:1) in 111 patients with persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cavity cancer. The trial did not meet its primary endpoint of demonstrating a statistically significant improvement in PFS for patients treated with cabozantinib as compared to paclitaxel. Safety data were consistent with those observed in other trials of cabozantinib. The results of the study are the subject of ongoing analyses and will be submitted by the investigators for presentation at a future medical conference.
- NCI-CTEP anticipates in the near-term the initiation of a phase 1 trial of cabozantinib in combination with nivolumab alone, or in combination with nivolumab plus ipilimumab, in patients with advanced/metastatic urothelial (bladder) and other genitourinary tumors.

Ongoing Planning for Potential Commercialization of Cobimetinib. Exelixis and Genentech continue to make progress in planning for the potential commercialization of cobimetinib following the February 2015 acceptance of Genentech's NDA for cobimetinib, to be used in combination with vemurafenib for patients with advanced melanoma harboring a BRAF V600 mutation. The FDA granted Priority Review to the NDA and assigned a Prescription Drug User Fee Act Action Date of August 11, 2015. In the European Union, Roche filed a Marketing Authorization Application for cobimetinib used in combination with vemurafenib in September of 2014. Cobimetinib, a selective MEK inhibitor, is the subject of a worldwide collaboration agreement between Exelixis and Genentech. Pursuant to this agreement, Exelixis is entitled to an initial equal share of U.S. profits and losses, with our share decreasing as sales increase. The parties will share equally in the U.S. marketing and commercialization costs, and, if approved, Exelixis will co-promote the compound in the U.S. Outside the U.S., Exelixis is entitled to receive royalties on sales of cobimetinib.

Exelixis-Discovered Compounds at the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO). Cabozantinib will be the subject of eight presentations at ASCO, comprising updates from clinical trials in multiple tumor types, including triple-negative breast cancer and non-small cell lung cancer. Cobimetinib will be the subject of six presentations, including updates from the coBRIM and BRIM7 clinical trials in metastatic melanoma.

Product Revenue from COMETRIQ. Net product revenue from COMETRIQ® (cabozantinib capsules) sales was $9.4 million for the first quarter of 2015, an increase of 91% over the first quarter of 2014, reflecting the continued ramp up in sales of the product following its commercial launch in the United States in January 2013. Net product revenue for the first quarter of 2015 includes the impact of a one-time adjustment of $2.6 million due to the conversion from the sell-through to sell-in method of revenue recognition. Going forward, product revenue will be recognized on the sell-in method of

revenue recognition.

2015 Financial Guidance. The key milestones that Exelixis anticipates later this year will influence operating expenses for the remainder of 2015. Accordingly, the company is currently only providing guidance for the first six months of 2015. The company anticipates that operating expenses for the first six months of 2015 will be in a range of $70 million to $80 million, including approximately $2 million in restructuring charges primarily related to building exit costs.

On March 4, 2015, Exelixis provided Deerfield notice of the company's election to extend the maturity date of the Deerfield Notes to July 1, 2018, according to the terms of the note purchase agreement, as amended. Per those terms, the extension of the Deerfield Notes is expected to occur on July 1, 2015, subject to customary closing conditions, including the accuracy of the company's representations and warranties set forth in the note purchase agreement, as of July 1, 2015. Assuming the anticipated extension of the maturity date of the Deerfield Notes to July 1, 2018, Exelixis expects that its current cash and cash equivalents, short- and long-term investments and product revenues are sufficient to fund its operations through the end of the first quarter of 2016.

"In the first quarter, the Exelixis team made strong progress toward the multiple clinical and regulatory milestones that are anticipated throughout 2015," said Michael M. Morrissey, Ph.D., the company's president and chief executive officer. "The company's top priority remains the delivery of top-line results from METEOR, the phase 3 pivotal trial of cabozantinib in mRCC. If METEOR is successful, we will turn our focus to completing U.S. and EU regulatory filings by early 2016."

Dr. Morrissey continued: "We are also looking forward to a significant presence at the upcoming ASCO conference, with several key presentations for both cabozantinib and cobimetinib, including oral presentations of data from a phase 2 study of cabozantinib in non-small cell lung cancer and updated PFS data from the pivotal phase 3 study of cobimetinib, coBRIM. In addition, we continue to make progress in our preparation for the potential commercialization of cobimetinib with our partners Roche and Genentech. As Exelixis nears the midpoint of an impactful year, we are committed to maximizing the value of the opportunities in front of us. As always, we also remain grateful for the support of our stakeholders who believe, as we do, that our compounds have the potential to meaningfully improve cancer care."

First Quarter 2015 Financial Results

Net revenues for the quarter ended March 31, 2015 were $9.4 million, compared to $4.9 million for the comparable period in 2014. Net revenues consisted entirely of product revenue related to the sale of COMETRIQ.

Research and development expenses for the quarter ended March 31, 2015 were $22.3 million, compared to $54.8 million for the comparable period in 2014. The decrease was primarily related to a net decrease in clinical trial costs, predominantly due to decreases in costs related to COMET-1 and COMET-2, our phase 3 pivotal trials in metastatic castration-resistant prostate cancer, a $7.5 million comparator drug purchase that occurred for the quarter ended March 31, 2014 for METEOR (there was no such purchase for the quarter ended March 31, 2015) and decreases in personnel related expenses for the quarter ended March 31, 2015. Those decreases were partially offset by increases in other costs related to METEOR for the quarter ended March 31, 2015.

Selling, general and administrative expenses for the quarter ended March 31, 2015 were $9.5 million, compared to $14.7 million for the comparable period in 2014. The decrease was primarily related to a decrease in personnel expenses resulting from an overall reduction in headcount, consulting and outside services, and legal and patent costs. Those decreases were partially offset by higher marketing expenses, including expenses for cobimetinib under the company's collaboration agreement with Genentech.

Restructuring credit for the quarter ended March 31, 2015 was $0.4 million. The restructuring credit was primarily related to recoveries recorded from the sale of assets removed from service as a result of our restructuring plans.

Other income (expense), net for the quarter ended March 31, 2015 was a net expense of ($12.4) million compared to ($9.6) million for the comparable period in 2014. The net expense is comprised primarily of interest expense which includes $7.7 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 the Deerfield Notes for the quarter ended March 31, 2015, as compared to $7.0 million for the comparable period in 2014.

Net loss for the quarter ended March 31, 2015 was ($35.2) million, or ($0.18) per share, basic, compared to ($74.6) million, or ($0.39) per share, basic, for the comparable period in 2014. The decreased net loss for the quarter was primarily due to decreases in research and development expenses and selling, general and administrative expenses and an increase in product revenues.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $197.6 million at March 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 first quarter of 2015 and provide a general business update during a conference call beginning at 5:00 p.m. EDT/2:00 p.m. PDT today, April 30, 2015. To join the call, participants may dial 855-793-2457 (domestic) or 631-485-4921 (international) and provide the conference call passcode 20896617 to join by phone. To listen to a live webcast of the conference call, visit the Event Calendar page under Investors & Media at www.exelixis.com.

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. EDT on May 2, 2015. Access numbers for the phone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 20896617.

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 COMETRIQ® (cabozantinib capsules), its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a selective inhibitor of MEK, 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 web site at www.exelixis.com.

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 April 3, 2015, January 2, 2015 and March 28, 2014 are indicated as being as of and for the periods ended March 31, 2015, December 31, 2014 and March 31, 2014, respectively. The quarter ended January 2, 2015 is a 14-week fiscal quarter; all other interim periods presented are 13-week fiscal quarters.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the continued development and clinical, therapeutic and commercial potential of, and opportunities for, cabozantinib and cobimetinib; potential eligibility for Priority Review of an NDA for cabozantinib as a treatment for patients with advanced RCC who have received one prior therapy; anticipated developments and timing with respect to Exelixis' ongoing phase 3 pivotal trials of cabozantinib and trials of cabozantinib being conducted through Exelixis' collaborators at NCI-CTEP and independent investigators; the progress of Exelixis' commercialization planning and preparation efforts with Genentech; cobimetinib regulatory filings and future potential approvals; the financial terms of the collaboration agreement between Exelixis and Genentech; future data presentations of cabozantinib and cobimetinib; Exelixis' plan to recognize product revenue on the sell-in method going forward; Exelixis' financial outlook for the first six months of 2015, including projected operating expenses; the sufficiency of Exelixis' cash resources to fund its operations through the end of the first quarter of 2016; the expected extension of the maturity date of Exelixis' indebtedness under its note purchase agreement with Deerfield to July 1, 2018 from July 1, 2015; future potential regulatory filings for cabozantinib if METEOR is successful; and Exelixis' belief that its compounds have the potential to meaningfully improve cancer care. Words such as "continues," "focus," " potential," "will," "anticipates," "initiation," "expects," "delivery," "looking forward," "believe," "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. Exelixis' 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 availability of data at the expected times; risks related to the potential failure of cabozantinib, cobimetinib and other Exelixis compounds to demonstrate safety and efficacy in clinical testing; the clinical, therapeutic and commercial value of cobimetinib, cabozantinib and other Exelixis compounds; Exelixis' dependence on its relationship with Genentech/ Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; the uncertainty of regulatory approval processes; the sufficiency of Exelixis' capital and other resources; the uncertain timing and level of expenses associated with the development of cabozantinib; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; Exelixis' ability to extend the maturity date of its indebtedness under its note purchase agreement with Deerfield in accordance with, and subject to, the terms and conditions of the note purchase agreement; 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; risks and uncertainties related to Exelixis' compliance with applicable regulatory requirements, including healthcare fraud and abuse laws and post-marketing requirements; Exelixis' dependence on third-party vendors; 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 April 30, 2015 and in Exelixis' other filings with the SEC. 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 March 31,	
	2015	**2014**
Revenues:		
Net product revenues	$ 9,388	$ 4,905
Operating expenses:		
Cost of goods sold	766	309
Research and development	22,282	54,847
Selling, general and administrative	9,531	14,691
Restructuring (credit) charge	(431)	46
Total operating expenses	32,148	69,893
Loss from operations	(22,760)	(64,988)
Other income (expense), net:		
Interest income and other, net	(7)	2,131
Interest expense	(12,403)	(11,762)
Total other income (expense), net	(12,410)	(9,631)

Net loss	$ (35,170)	$ (74,619)
Net loss per share, basic and diluted	$ (0.18)	$ (0.39)
Shares used in computing basic and diluted net loss per share	195,904	191,699

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

	March 31, 2015 (unaudited)	**December 31, 2014** (1)
Cash and investments (2)	$ 197,634	$ 242,760
Working capital	$ 66,360	$ (4,619)
Total assets	$ 282,934	$ 327,960
Total stockholders' deficit	$ (146,759)	$ (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. Short- and long-term restricted cash and investments totaled $8.8 million and $16.9 million as of March 31, 2015 and December 31, 2014, respectively.

Source: Exelixis, Inc.

Exelixis, Inc.
Deborah Burke, 650-837-7835
Chief Financial Officer
dburke@exelixis.com
or
Susan Hubbard, 650-837-8194
Investor Relations & Corporate Communications
shubbard@exelixis.com