Exelixis Announces Fourth Quarter and Full Year 2014 Financial Results and Provides Corporate Update

February 24, 2015

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 24, 2015-- Exelixis, Inc. (Nasdaq:EXEL) today reported financial results for the fourth quarter and full year of 2014 and provided an update on progress toward delivering upon its 2015 key corporate objectives and clinical development milestones.

Corporate Updates and Key Priorities for 2015

In 2015, Exelixis will continue 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.

Top-Line Results for METEOR Trial in mRCC Expected in Q2 2015. The company's top clinical development priority is the delivery of top-line data for METEOR, the phase 3 pivotal trial of cabozantinib in mRCC. Enrollment in METEOR was completed in November 2014, and Exelixis expects top-line results from the trial's primary endpoint, progression-free survival (PFS), in the second quarter of this year. Per the trial protocol, the primary PFS endpoint analysis will be conducted once 259 events have occurred among the first 375 patients enrolled. Enrollment for the first 375 patients in METEOR was completed in June 2014.

Cobimetinib U.S. and EU Regulatory Progress. As announced earlier this month, the U.S. Food & Drug Administration (FDA) has accepted for review Genentech's New Drug Application (NDA) for cobimetinib, an Exelixis-discovered compound, to be used in combination with vemurafenib as a treatment for patients with BRAF V600 mutation-positive advanced melanoma. The FDA granted Priority Review to the NDA and assigned a Prescription Drug User Fee Act Action Date of August 11, 2015. Cobimetinib is the subject of a worldwide co-development agreement between Exelixis and Genentech. Pursuant to this agreement, Exelixis is entitled to an initial equal share of U.S. profits and losses, which share will decrease 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. In the European Union, Roche filed a Marketing Authorization Application for cobimetinib used in combination with vemurafenib in September of 2014.

Genentech has also initiated a series of early clinical studies evaluating the potential of cobimetinib in combination with other compounds in its oncology pipeline, including the anti-PDL1 antibody MPDL3280A, and in other solid tumor types, including non-small cell lung cancer (NSCLC), colorectal cancer and triple-negative breast cancer.

Broad Cabozantinib Development Program Continues to Expand through NCI and Independent Investigators. While Exelixis pursues cabozantinib's late-stage development in mRCC 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. Key anticipated milestones for the NCI-CTEP program expected to be reached in the first half of 2015 include: top-line data from a randomized phase 2 trial of cabozantinib versus paclitaxel in second or later line persistent or recurrent ovarian cancer; detailed data from a randomized phase 2 trial of cabozantinib with and without erlotinib compared to erlotinib alone in second or third line EGFR wild-type NSCLC; completion of enrollment of a randomized phase 2 study of cabozantinib versus sunitinib in first-line RCC; and the initiation by the NCI of a combination phase 1b study of cabozantinib and nivolumab with or without ipilimumab in urothelial cancer.

Advancing Other Pipeline and Partnered Programs. Beyond cabozantinib and cobimetinib, other Exelixis-discovered compounds continue to advance. In November, independent investigators at the Moffitt Cancer Center (Tampa, Florida) presented positive preliminary data from a phase 1 trial of XL888, the company's wholly-owned small molecule oral inhibitor of Heat Shock Protein 90 (HSP90), in combination with vemurafenib in patients with BRAF V600 mutation-positive melanoma. Based on those results, as well as the data from cobimetinib's pivotal trial, the investigators plan to initiate a phase 1b IST of vemurafenib, cobimetinib, and XL888 in a similar population this year.

Separately, Exelixis' partner Daiichi-Sankyo has recently initiated two large phase 2b trials of CS-3150 (XL550), from Exelixis-discovered compounds, in Japanese patients with hypertension and diabetic nephropathy, respectively. CS-3150 is a small molecule antagonist of the mineralocorticoid receptor, a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. Exelixis out-licensed the compounds to Daiichi-Sankyo in 2006 and is eligible to receive additional development, regulatory and commercialization milestone payments, as well as royalties on any potential product sales.

COMETRIQ Product Revenue and European Commercialization. Net product revenue from COMETRIQ® (cabozantinib capsules) sales was $7.4 million for the fourth quarter of 2014, an increase of 69 percent over the fourth quarter of 2013, reflecting the continued ramp up in sales of the product following its commercial launch in the United States in January 2013 and further uptake of COMETRIQ in certain countries of the European Union following its approval in March 2014. Net product revenue for the fourth quarter of 2014 includes the impact of a project management fee of $0.5 million payable to Exelixis' European distribution partner, Swedish Orphan Biovitrum AB (Sobi), upon its achievement of a cumulative revenue goal.

Exelixis and Sobi continue to make progress on the European commercialization of COMETRIQ following its EU approval in March 2014. Last month, Exelixis and Sobi announced an extended and restructured agreement to support the distribution and commercialization of COMETRIQ for its medullary thyroid cancer indication in the EU, Switzerland, Norway, Russia, and Turkey. The agreement, which was established in February 2013 and due to expire on December 31, 2015, will now extend to December 31, 2019. Moreover, the payment structure of the partnership will transition from

fixed fees paid by Exelixis to Sobi to support initial build out of COMETRIQ European commercial infrastructure to a sales margin-based approach. COMETRIQ is now commercially available in Germany, Wales, England, Sweden, Finland, Denmark, Norway, Czech Republic, Austria and The Netherlands, and Sobi anticipates additional European launches during the course of 2015 and beyond as pricing and reimbursement are achieved.

2015 Financial Guidance. Given that Exelixis anticipates key clinical milestones in the second quarter of this year that will influence operating expenses for the remainder of 2015, 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 to be in a range of $70 million to $80 million. This range includes approximately $5 million in restructuring charges in the first half of 2015 primarily related to building exit costs. Taking into account the expected extension of the maturity date of the company's indebtedness under its note purchase agreement with Deerfield to July 1, 2018 from July 1, 2015, 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 2015. Exelixis has until March 31, 2015 to exercise its option to extend the maturity date of the Deerfield indebtedness, as provided for by the January 2014 amendment to the note purchase agreement. Any exercise of the extension option by Exelixis will be subject to customary conditions set forth in the note purchase agreement, as amended.

"In 2015, Exelixis anticipates multiple clinical development and regulatory milestones that have the potential to significantly shape our company's path forward and positively impact the patients, clinicians and other stakeholders we serve," said Michael M. Morrissey, Ph.D., the company's president and chief executive officer. "In the second quarter, we expect top-line results from the METEOR phase 3 pivotal trial, which, if positive, would represent considerable progress for Exelixis towards delivering a new and meaningfully differentiated therapeutic option for patients with mRCC. In the third quarter, we anticipate an FDA decision on Genentech's NDA for cobimetinib for use in combination with vemurafenib. Such an approval would represent both a substantial advance for the melanoma community and a valuable opportunity for Exelixis to work alongside Genentech to co-promote cobimetinib in the United States."

Dr. Morrissey continued: "While Exelixis maintains its close focus on cabozantinib's ongoing pivotal trials, our collaborators continue to evaluate cabozantinib, and other Exelixis-discovered compounds, in a variety of settings. We look forward to the planned readout and presentation of trials evaluating cabozantinib in ovarian cancer and EGFR wild type NSCLC this year, and to the Moffitt Cancer Center's initiation of the planned triple-combination trial of XL888, vemurafenib, and cobimetinib. We are steadfast in our commitment to seek to maximize the value of our oncology assets through our clinical and commercial efforts, and we remain grateful for our stakeholders' support as we work to make meaningful contributions to improving cancer care."

Fourth Quarter and Full Year 2014 Financial Results

Net revenues for the quarter ended December 31, 2014 were $7.4 million, compared to $4.3 million for the comparable period in 2013; and for the year ended December 31, 2014 were $25.1 million, compared to $31.3 million for the comparable period in 2013. Net revenues in 2014 consisted entirely of product revenue related to the sale of COMETRIQ and were net of a project management fee payable to Exelixis' European distribution partner of $0.5 million for the fourth quarter of 2014 and $2.3 million for the year ended December 31, 2014; no such fees were recognized during the comparable periods in 2013. Net revenues in 2013 consisted of $15.0 million of product revenue and $16.3 million of license and contract revenue. The decrease in contract and license revenue reflects the company's full recognition of all revenues from its collaboration agreements with Bristol-Myers Squibb Company in the third quarter of 2013.

Research and development expenses for the quarter ended December 31, 2014 were $39.7 million, compared to $49.6 million for the comparable period in 2013; for the year ended December 31, 2014 were $189.1 million, compared to $178.8 million for the comparable period in 2013. The decrease for the quarter ended December 31, 2014 as compared to the same period in 2013 primarily related to a decrease in personnel expenses resulting from an overall reduction in headcount and the elimination of employee bonuses as well as a related reduction in stock-based compensation expense; in addition, clinical trial costs decreased predominantly due to a reduction in costs related to COMET-1, which was offset in part by increases in costs related to METEOR and CELESTIAL, Exelixis' phase 3 pivotal trial in advanced HCC. The overall increase in research and development expenses for the year ended December 31, 2014 as compared to 2013 was primarily due to increased clinical trial costs, and related temporary, consulting and outside servicing costs in support of METEOR. These increased costs were partially offset by a reduction in costs related to COMET-1 and were further offset by decreases in personnel expenses resulting in part from the elimination of employee bonuses and a reduction in stock-based compensation expense.

Selling, general and administrative expenses for the quarter ended December 31, 2014 were $9.8 million, compared to $13.6 million for the comparable period in 2013; and for the year ended December 31, 2014 were $50.8 million, compared to $51.0 million for the comparable period in 2013. The decrease for the quarter ended December 31, 2014, as compared to 2013, was primarily related to a decrease in personnel expenses resulting from an overall reduction in headcount and the elimination of employee bonuses as well as lower consulting and outside services fees. For the year ended December 31, 2014, as compared to 2013, decreases in consulting and outside services fees and legal costs were offset by increased personnel expenses, the majority of which are associated with the expansion of the company's U.S. sales force and higher marketing expenses, including an increase in expenses for cobimetinib under the company's collaboration agreement with Genentech.

Restructuring charge for the quarter ended December 31, 2014 was $3.5 million compared to $0.4 million for the comparable period in 2013; and for the year ended December 31, 2014 was $7.6 million compared to $1.2 million for the comparable period in 2013. The restructuring charge for the quarter and year ended December 31, 2014 was primarily related to employee termination benefits and asset impairment charges resulting from the restructuring plan initiated in September 2014.

Other income (expense), net for the quarter ended December 31, 2014 was a net expense of ($11.9) million compared to ($11.3) million for the comparable period in 2013; and for the year ended December 31, 2014 was a net expense of ($44.3) million compared to ($44.1) million for the comparable period in 2013. The slight increase in expense for both the quarter and year ended December 31, 2014 is primarily due to interest expense which includes $7.7 million and $29.5 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 its note purchase agreement with Deerfield, as compared to $6.8 million and $26.3 million, respectively, for the comparable periods in 2013.

Income tax benefit for the quarter and year ended December 31, 2014 of $0.2 million resulted from state tax benefit related to the lapse of the applicable statute of limitations in California for the 2009 tax year, offset by current year state income tax expense.

Net loss for the quarter ended December 31, 2014 was ($58.0) million, or ($0.30) per share, basic, compared to ($70.7) million, or ($0.38) per share,

basic, for the comparable period in 2013; and for the year ended December 31, 2014 was ($268.5) million, or ($1.38) per share, basic, compared to ($244.8) million, or ($1.33) per share, basic, for the comparable period in 2013. 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, which was partially offset by an increase in restructuring charges. The increased net loss for the year was primarily due to decreases in contract and license revenue, increases in research and development expenses and restructuring charges, which was partially offset by an increase in product revenues.

Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments totaled $242.8 million at December 31, 2014, compared to $415.9 million at December 31, 2013.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the quarter and full year ended December 31, 2014 and provide a general business update during a conference call beginning at 5:00 p.m. EST/2:00 p.m. PST today, February 24, 2015. To join the call, participants may dial 1-877-546-5020 (domestic) or 1-857-244-7552 (international) and use passcode 38677626. 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. EST on February 26, 2015. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 64033209.

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), its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a highly 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 quarters and years ended January 2, 2015 and December 27, 2013 are indicated as ended December 31, 2014 and December 31, 2013, 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, cobimetinib and other Exelixis-discovered compounds; anticipated developments and timing with respect to Exelixis' ongoing phase 3 pivotal trials of cabozantinib; future cobimetinib regulatory filings and potential approvals; the progress of Exelixis' commercialization planning and preparation efforts with Genentech; the progress of the European commercialization of COMETRIQ® (cabozantinib); continuing investigation of cabozantinib through Exelixis' collaborations with the NCI-CTEP and the ongoing IST program; future data presentations and clinical trial planning; 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 2015; 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; and the timing of future reporting on Exelixis' progress. Words such as "continues," "expects," "anticipate," "will," "plan," "initiate," "potential," "focus," "delivery," "committed," "look forward," 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-discovered compounds to demonstrate safety and efficacy in clinical testing; the clinical, therapeutic and commercial value of cobimetinib, cabozantinib and other Exelixis-discovered 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 November 4, 2014, as updated by Exelixis' annual report on Form 10-K to be filed with the SEC not later than March 3, 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 December 31,		Year Ended December 31,	
	2014	**2013**	**2014**	**2013** (1)
Revenues:				
Net product revenues	$ 7,353	$ 4,347	$ 25,111	$ 15,017
License and contract revenues	—	—	—	16,321
Total revenues	7,353	4,347	25,111	31,338
Operating expenses:				
Cost of goods sold	684	263	2,043	1,118
Research and development	39,650	49,597	189,101	178,763
Selling, general and administrative	9,766	13,635	50,829	50,958
Restructuring charge	3,461	366	7,596	1,231
Total operating expenses	53,561	63,861	249,569	232,070
Loss from operations	(46,208)	(59,514)	(224,458)	(200,732)
Other income (expense), net:				
Interest income and other, net	555	293	4,341	1,223
Interest expense	(12,482)	(11,621)	(48,607)	(45,347)
Total other income (expense), net	(11,927)	(11,328)	(44,266)	(44,124)
Loss before income taxes	(58,135)	(70,842)	(268,724)	(244,856)
Income tax benefit	(182)	(96)	(182)	(96)
Net loss	$ (57,953)	$ (70,746)	$ (268,542)	$ (244,760)
Net loss per share, basic and diluted	$ (0.30)	$ (0.38)	$ (1.38)	$ (1.33)
Shares used in computing basic and diluted net loss per share	195,536	184,376	194,299	184,062

(1) Derived from the audited consolidated financial statements.

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

	December 31, 2014 (unaudited)	**December 31, 2013** (1)
Cash and investments (2)	$ 242,760	$ 415,862
Working capital	$ (4,619)	$ 178,756
Total assets	$ 327,960	$ 503,287
Total stockholders' (deficit) equity	$ (114,829)	$ 66,238

(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 $16.9 million and $29.1 million as of December 31, 2014 and December 31, 2013, respectively.

Source: Exelixis, Inc.

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