



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

November 3, 2016

- Cabozantinib Franchise Net Product Revenues of \$42.7 Million -

- Total Revenues of \$62.2 Million -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 3, 2016-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the third 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 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. CABOMETYX generated \$31.2 million in net product revenue during the third quarter of 2016, which reflects the first full quarter of product sales. Net product revenues for the third quarter of 2016, including sales of COMETRIQ® (cabozantinib) capsules for the treatment of certain forms of thyroid cancer, were \$42.7 million. While Exelixis focuses on commercialization in the United States, its partner Ipsen is in the process of launching CABOMETYX in the European Union, following the European Commission's (EC) September 2016 approval of CABOMETYX for the treatment of adult patients with advanced RCC who have received prior vascular endothelial growth factor (VEGF)-targeted therapy. Exelixis is eligible to receive royalties on CABOMETYX sales by Ipsen outside of the United States, Canada and Japan.

"The third quarter of 2016 was an important inflection point for Exelixis. We recorded our first full quarter of CABOMETYX sales and also made significant progress on our path towards becoming a profitable, fully integrated, commercial biopharmaceutical company," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Feedback from prescribers, as well as performance to date, suggest that clinicians treating advanced renal cell carcinoma see CABOMETYX as a differentiated therapy and are increasingly incorporating it into their practice. While we continued to execute on the U.S. CABOMETYX launch and pursue important clinical trials like CABOSUN that have the potential to further advance our business, we also demonstrated sound fiscal discipline, resulting in a significantly decreased net loss and cash burn. As we close out the year, we remain committed to maximizing our opportunity to improve the treatment of cancer while building a strong and nimble company."

Cabozantinib Highlights

Presented Positive Results from Phase 2 CABOSUN Trial in Advanced RCC. At the European Society for Medical Oncology (ESMO) 2016 Congress, detailed results were presented from CABOSUN, the randomized phase 2 trial of cabozantinib compared with sunitinib in patients with previously untreated advanced RCC with intermediate- or poor-risk disease per the International Metastatic Renal Carcinoma Database Consortium risk criteria. In this trial, cabozantinib demonstrated a statistically significant and clinically meaningful reduction in the rate of disease progression or death as compared to sunitinib. The CABOSUN results were the subject of a late-breaking abstract at ESMO, and were highlighted at one of the Congress' Presidential Symposia and in its official media program. CABOSUN was conducted by The Alliance for Clinical Trials in Oncology with support from the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP).

Plans for Supplemental New Drug Application in First-Line Advanced RCC. Based on the CABOSUN results, Exelixis plans to submit a Supplemental New Drug Application (sNDA) for cabozantinib as a treatment for previously untreated advanced RCC. The company is working with The Alliance to transfer the complete CABOSUN clinical database to Exelixis and will facilitate an independent radiological review of the CABOSUN imaging data in preparation for filing.

Phase 1 Trial Results for Cabozantinib in Combination with Nivolumab in Advanced Genitourinary Tumors. Also at the ESMO 2016 Congress, positive results were presented from the NCI-CTEP-sponsored phase 1 trial of cabozantinib in combination with nivolumab in patients with previously treated genitourinary tumors. Part II of the study is evaluating the triplet combination of cabozantinib, nivolumab, and ipilimumab and thus far has enrolled 15 patients. Expansion cohorts assessing cabozantinib and nivolumab, including patients with bladder, renal, and rare genitourinary cancers, are also currently being accrued.

European Commission Approval of CABOMETYX for the Treatment of Advanced RCC. On September 9, 2016, the EC approved CABOMETYX for the treatment of advanced RCC in adults following prior VEGF-targeted therapy. The approval allows for the marketing of CABOMETYX in all 28 member states of the European Union, Norway and Iceland. Under the license agreement with Ipsen, the EC approval triggered a \$60.0 million milestone payment from Ipsen to Exelixis, which is expected to be received in the fourth quarter of 2016.

Outcome from First Planned Interim Analysis of Phase 3 CELESTIAL Trial. On September 6, 2016, Exelixis announced the outcome from the first planned interim analysis of CELESTIAL, the randomized global phase 3 trial of cabozantinib compared with placebo in patients with advanced hepatocellular carcinoma who have been previously treated with sorafenib. Following the analysis, the trial's Independent Data Monitoring Committee determined that the study should continue without modifications per the study protocol. The trial protocol calls for a second interim analysis to take place once 75 percent of planned events have been observed.

Cobimetinib Highlights

Results from Cobimetinib Combination Trials Support Further Advancement. Cobimetinib, the Exelixis-discovered MEK inhibitor now the subject of a worldwide collaboration with Genentech, a member of the Roche Group, was the subject of seven presentations at the ESMO 2016 Congress. For

the first time, investigators presented preliminary results from the phase 1b clinical trial of the triple combination of cobimetinib, vemurafenib, and atezolizumab in patients with previously untreated BRAF V600 mutation-positive advanced melanoma. The regimen was associated with promising antitumor activity and a manageable safety profile; details of a subsequent Roche-sponsored phase 3 pivotal trial, TRILOGY, have been posted to www.ClinicalTrials.gov. Investigators also presented updated results from the phase 1 trial of cobimetinib plus atezolizumab in advanced colorectal cancer that provide a rationale for COTEZO, the ongoing phase 3 pivotal trial in the same disease setting. New data from the phase 1 part of COLET, the phase 1/2 trial of cobimetinib and paclitaxel in triple-negative breast cancer, were also the subject of a poster presentation at the meeting.

Corporate Highlights

Exelixis Presence at the ESMO 2016 Congress. Exelixis-discovered compounds were the subject of 15 presentations at the ESMO 2016 Congress, which was held October 7-11 in Copenhagen, Denmark. The company also hosted an investor/analyst briefing in which management and invited guests discussed the cabozantinib data at the meeting, including CABOSUN and the combination trial of cabozantinib and nivolumab in advanced genitourinary tumors. For full details, see the August 31st abstract acceptance press release, the subsequent data press releases, and the replay of the briefing on www.exelixis.com.

Addition to the Exelixis Board of Directors. On September 22, 2016, Exelixis named Julie Anne Smith to the company's Board of Directors. Ms. Smith joins the Exelixis board with nearly two decades of operational leadership experience in high growth public, private, startup, and established biopharmaceutical businesses. She served as President and Chief Executive Officer of Raptor Pharmaceuticals, a commercial-stage, global innovator in the development and commercialization of orphan disease therapies, from January 2015 through the company's acquisition by Horizon Pharma plc, or Horizon. Ms. Smith is continuing to provide transition services to Horizon through December 31, 2016.

Phase 3 Clinical Development for CS-3150. On September 26, 2016, Exelixis announced its partner Daiichi Sankyo initiated a phase 3 pivotal trial to evaluate CS-3150 (esaxerenone (r-INN)), an oral, non-steroidal, selective mineralocorticoid receptor antagonist, as a treatment for essential hypertension in Japanese patients. Enrollment of the trial's first patient made Exelixis eligible to receive a \$15.0 million milestone payment, which it received in the fourth quarter of 2016. CS-3150 is one of the compounds identified during Exelixis' prior research collaboration with Daiichi Sankyo.

Conversion and Redemption of 4.25% Convertible Senior Subordinated Notes. On August 9, 2016 and August 19, 2016, respectively, Exelixis entered into separate, privately negotiated exchange transactions with certain holders of the 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes. Under the terms of the associated exchange agreements, the holders agreed to convert an aggregate principal amount of \$239.4 million of 2019 Notes held by them in exchange for an aggregate of 45,064,456 shares of Exelixis common stock and an aggregate cash payment of approximately \$2.4 million. Following completion of the exchange transactions, on August 24, 2016, Exelixis provided public notice of the redemption of the final \$48.1 million of the 2019 Notes, representing all remaining notes outstanding. Following a required redemption period, holders of the remaining 2019 Notes had the option to convert their notes into shares of Exelixis common stock, plus cash in lieu of any fractional share, at a conversion rate of 188.2353 shares of common stock per \$1,000 principal amount of their notes at any time before close of business on October 31, 2016. During the required redemption period, \$47.5 million of the 2019 Notes were converted into shares of Exelixis common stock and the remaining \$0.6 million of the 2019 Notes outstanding on November 2, 2016 were redeemed in cash for 100% of the principal amount thereof, plus accrued and unpaid interest to, but excluding such date.

2016 Financial Guidance

The company is refining its guidance that operating expenses for the full year 2016 will be approximately \$245 million, including approximately \$25 million of non-cash items primarily related to stock-based compensation expense.

Third Quarter 2016 Financial Results

Total revenues for the quarter ended September 30, 2016 were \$62.2 million, compared to \$9.9 million for the comparable period in 2015. Total revenues for the third quarter of 2016 include \$42.7 million of net product revenue compared to \$6.9 million for the comparable period in 2015. The increase in net product revenues for the three months ended September 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 \$31.2 million and \$11.5 million, respectively. Total revenues for the quarter ended September 30, 2016 include the recognition of \$15.0 million of contract revenue from the Daiichi Sankyo CS-3150 milestone, \$3.8 million of license revenues recognized under Exelixis' collaboration and license agreement with Ipsen and \$0.7 million of royalties on ex-U.S. net sales of COTELLIC[®] (cobimetinib). There was \$3.0 million of contract revenues for a milestone payment received from Merck related to their worldwide license of Exelixis' PI3K-delta program during the comparable period in 2015.

Research and development expenses for the quarter ended September 30, 2016 were \$20.3 million, compared to \$26.1 million for the comparable period in 2015. The decrease was primarily related to decreases in share-based compensation, 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 the Exelixis Medical Affairs organization.

Selling, general and administrative expenses for the quarter ended September 30, 2016 were \$32.5 million, compared to \$17.8 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 connected with the build-out of the Exelixis U.S. commercial organization, marketing and outside services to support the launch and commercialization of CABOMETYX.

Other income (expense), net for the quarter ended September 30, 2016 was a net expense of (\$18.5) million compared to (\$9.8) million for the comparable period in 2015. The increase in net expense was primarily due to the \$13.8 million of loss associated with the conversion through September 30, 2016 of \$285.3 million in aggregate principal amount of the company's 2019 Notes for 53,704,911 shares of our common stock. The net expense also includes interest expense which includes \$3.9 million of non-cash expense related to the accretion of the discounts on both the 2019 Notes and the company's indebtedness under its Secured Convertible Notes due 2018 held by entities associated with Deerfield for the quarter ended September 30, 2016, as compared to \$4.9 million for the comparable period in 2015.

Net loss for the quarter ended September 30, 2016 was (\$11.3) million, or (\$0.04) per share, basic, compared to (\$45.5) million, or (\$0.21) per share, basic, for the comparable period in 2015. The decreased net loss for the quarter was primarily due to increases in net revenues and a decrease in

research and development expenses, which were partially offset by increases in selling, general and administrative expenses and other income (expense), net.

Cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments totaled \$379.6 million at September 30, 2016, which increased from \$253.3 million at December 31, 2015.

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 September 30, 2016, January 1, 2016 and October 2, 2015 are indicated as being as of and for the periods ended September 30, 2016, December 31, 2015 and September 30, 2015, respectively.

Correction of an Immaterial Error

Certain historical amounts in other income (expense), net, net loss and stockholders' equity (deficit) presented herein have been revised to reflect the correction of the accounting for non-cash interest expense associated with the 2019 Notes. See "Note 1 - Organization and Summary of Significant Accounting Policies" to Exelixis' Condensed Consolidated Financial Statements included in Exelixis' quarterly report on Form 10-Q for the quarterly period ended September 30, 2016 for a further description of this error and the historical amounts which have been corrected.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the third 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, Thursday, November 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 96160317 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on Saturday, November 5, 2016. Access numbers for the telephone replay are: (855) 859-2056 (domestic) and (404) 537-3406 (international); the passcode is 96160317. 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 CABOMETRYX™ tablets (U.S. and EU) 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 CABOMETRYX as a treatment for patients with advanced RCC; Exelixis' eligibility to receive royalties on CABOMETRYX sales by Ipsen outside of the United States, Canada and Japan; Exelixis' path towards becoming a profitable, fully integrated, commercial biopharmaceutical company; Exelixis' commitment to maximizing the company's opportunity to improve the treatment of cancer while building a strong and nimble company; Exelixis' plans to submit a sNDA for cabozantinib as a treatment for previously untreated advanced RCC and to facilitate an independent radiological review of the CABOSUN imaging data in preparation for the filing; the expected receipt of a \$60.0 million milestone payment from Ipsen in the fourth quarter of 2016; 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," "eligible," "path towards," "committed," "opportunity," "plans," "will," "expected," "guidance," "potential," 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 CABOMETRYX and COMETRIQ and the availability of coverage and reimbursement for CABOMETRYX and COMETRIQ; unanticipated developments that could adversely affect the commercialization of CABOMETRYX or COMETRIQ; the level of costs and expenses associated with Exelixis' commercialization, research and development and other activities; regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; 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; Exelixis' ability and the ability of its collaborators to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; 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 November 3, 2016, 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, the Exelixis logo, COMETRIQ and COTELLIC are registered U.S. trademarks, and CABOMETYX is a U.S. trademark.

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenues:				
Net product revenues	\$ 42,742	\$ 6,854	\$ 83,459	\$ 24,234
Royalty, license and contract revenues	19,452	3,000	30,414	3,000
Total revenues	<u>62,194</u>	<u>9,854</u>	<u>113,873</u>	<u>27,234</u>
Operating expenses:				
Cost of goods sold	2,455	1,420	4,700	2,872
Research and development	20,256	26,091	72,166	72,879
Selling, general and administrative	32,463	17,842	103,143	40,162
Restructuring (recovery) charge	(244)	282	871	1,142
Total operating expenses	<u>54,930</u>	<u>45,635</u>	<u>180,880</u>	<u>117,055</u>
Income (loss) from operations	<u>7,264</u>	<u>(35,781)</u>	<u>(67,007)</u>	<u>(89,821)</u>
Other income (expense), net:				
Interest income and other, net	3,059	276	4,010	146
Interest expense	(7,834)	(10,037)	(28,575)	(30,501)
Loss on extinguishment of debt	(13,773)	—	(13,773)	—
Total other income (expense), net	<u>(18,548)</u>	<u>(9,761)</u>	<u>(38,338)</u>	<u>(30,355)</u>
Net loss	<u>\$ (11,284)</u>	<u>\$ (45,542)</u>	<u>\$ (105,345)</u>	<u>\$ (120,176)</u>
Net loss per share, basic and diluted	\$ (0.04)	\$ (0.21)	\$ (0.44)	\$ (0.59)
Shares used in computing basic and diluted net loss per share	256,319	217,587	238,024	203,153

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	September 30,	
	2016	December 31,
	(unaudited)	2015 (1)
Cash and investments (2)	\$ 379,648	\$ 253,310
Working capital	\$ 219,685	\$ 126,414
Total assets	\$ 548,490	\$ 332,342
Total stockholders' equity (deficit)	\$ 32,022	\$ (140,806)

(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 September 30, 2016 and December 31, 2015, respectively.



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Source: Exelixis, Inc.

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