



Exelixis Announces First Quarter 2017 Financial Results and Provides Corporate Update

May 1, 2017

- Cabozantinib Franchise Net Product Revenues of \$68.9 Million, Total Revenues of \$80.9 Million -

- Achieves Profitability with Net Income of \$16.7 Million, Diluted EPS of \$0.05 per Share -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 1, 2017-- Exelixis, Inc. (Nasdaq:EXEL) today reported financial results for the first quarter of 2017 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

In 2017, Exelixis is focused on maximizing the opportunity for its two internally-discovered compounds, cabozantinib and cobimetinib, to improve care and outcomes for people with cancer around the world. The company's foremost priority is the ongoing 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. During the first quarter of 2017, CABOMETYX generated \$62.4 million in net product revenue, while COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional \$6.5 million in net product revenue, for a combined \$68.9 million in net product revenue for the cabozantinib franchise. In addition, Exelixis progressed its preparations to submit a supplemental New Drug Application (sNDA) for cabozantinib as a treatment for previously untreated patients with advanced RCC based on the positive data from the CABOSUN randomized phase 2 trial. Finally, Exelixis and its partner Genentech, a member of the Roche Group, are continuing to co-promote COTELLIC® (cobimetinib) in combination with vemurafenib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E mutation in the United States. Genentech continues to advance the cobimetinib clinical development program, and recently announced that IMblaze370, the phase 3 pivotal trial evaluating the combination of cobimetinib and atezolizumab in third-line advanced or metastatic colorectal cancer, achieved full enrollment in the first quarter of 2017. Two other phase 3 pivotal trials of combination regimens including cobimetinib are planned or underway in forms of advanced melanoma.

"The Exelixis team's progress this quarter is a launching point from which to build throughout 2017 as we work diligently to position the company as a sustainable business focused on improving the treatment of cancer for patients on a global basis," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "During the first quarter of 2017, we reached the important milestone for our shareholders of achieving profitability based on operations. In addition, we further advanced cabozantinib's commercialization and clinical development through our ongoing strong execution on the CABOMETYX U.S. launch, made additional progress in our preparations to submit a sNDA for previously untreated patients with advanced RCC, entered into important clinical development collaborations that will evaluate cabozantinib in combination with leading immunotherapies, and granted Japanese rights to a new cabozantinib partner, Takeda."

Dr. Morrissey continued: "Our partner Genentech moved cobimetinib, the second Exelixis-discovered compound, forward during the quarter as well, with the completion of enrollment in IMblaze370 in patients with advanced colorectal cancer. At Exelixis, we are focused on continuing to lay the groundwork for the future, including repaying our remaining debt this summer, planning to fund the company's growth from its operations, and assessing in-licensing opportunities and resuming internal drug discovery. We are committed to a plan that involves measured and judicious growth to put the company in the best position to help patients and build long-term value."

Cabozantinib Highlights

Strong Growth in Cabozantinib Franchise Net Revenues. Cabozantinib generated \$68.9 million in net product revenue during the first quarter of 2017, an increase of 33 percent from the fourth quarter of 2016 and an increase of 657 percent year-over-year. The year-over-year increase was driven primarily by the U.S. introduction of CABOMETYX following FDA approval in April 2016 as a treatment for patients with advanced RCC who have received prior anti-angiogenic therapy.

Partnership with Takeda for Japanese Commercialization and Development. In January 2017, Exelixis and Takeda jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib in Japan, including rights to CABOMETYX and COMETRIQ. Under the terms of the agreement, Exelixis received a \$50.0 million non-refundable upfront payment. Exelixis is eligible to receive development, regulatory, and first-sales milestones of \$95.0 million for the first three planned indications. In addition, Exelixis will be eligible to receive royalties on sales by Takeda. Takeda will be responsible for 20 percent of the costs associated with the global cabozantinib development plan's current and future trials, provided Takeda opts in to participate in such future trials, and 100 percent of costs associated with the cabozantinib development activities that are exclusively for the benefit of Japan.

Phase 1 Trial Results in Combination with Nivolumab and Ipilimumab in Advanced Genitourinary Tumors. At the ASCO Genitourinary Cancers Symposium in February 2017, investigators presented data from the phase 1 trial of cabozantinib in combination with nivolumab, with and without ipilimumab, in patients with previously treated genitourinary tumors including metastatic urothelial carcinoma and RCC. Data from this NCI-CTEP-sponsored study have informed the design of Exelixis and Bristol-Myers Squibb Company's (BMS) planned phase 3 pivotal trial of cabozantinib in combination with these therapies in first-line RCC, which is expected to start later this year.

Collaborations for Late-Stage Development in Combination with Immunotherapies. In February 2017, Exelixis announced agreements with BMS and Roche to collaborate on the development of cabozantinib in combination with immunotherapy agents. Exelixis and BMS announced their intent to collaborate on the evaluation of cabozantinib in combination with Opdivo® (nivolumab) alone or in combination with Yervoy® (ipilimumab) in a phase 3 trial in first-line RCC, and potentially in other tumor types including hepatocellular carcinoma (HCC) and bladder cancer. These studies are anticipated to begin in 2017. The collaborations build upon previously published preclinical and clinical data that underscore the scientific rationale for combining

cabozantinib with immunotherapies, and provide the resources and collaborative framework to evaluate the potential for cabozantinib combination regimens to benefit patients with a variety of cancers. Separately, Exelixis and Roche will collaborate to initiate the evaluation of cabozantinib in combination with Tecentriq® (atezolizumab), an anti-PD-L1 antibody, in patients with advanced RCC or bladder cancer. Ipsen has opted in to participate in the phase 3 pivotal trial in first-line advanced RCC with BMS and to participate in the study with Roche, and will have access to the results to support potential future regulatory submissions and for potential future development in its territories.

Continued Progress on Filing in Previously Untreated Advanced RCC. During the first quarter, Exelixis continued to make progress on its sNDA for cabozantinib as a treatment for previously untreated advanced RCC, and the company remains on track to complete the filing in the third quarter of 2017.

Orphan Drug Designation for HCC; Update on CELESTIAL Timelines. In March, the U.S. Food & Drug Administration (FDA) granted cabozantinib orphan drug designation for the treatment of HCC. A phase 3 pivotal trial (CELESTIAL) of cabozantinib is ongoing in patients with advanced HCC, and Exelixis is tracking events closely and now anticipates the second interim analysis at 75 percent of the events required will be completed in the second half of 2017.

Cobimetinib Highlights

IMblaze370 in Advanced Colorectal Cancer Completes Enrollment. Roche and Genentech recently announced that IMblaze370, the phase 3 pivotal trial evaluating the combination of cobimetinib and atezolizumab in third-line advanced or metastatic colorectal cancer, achieved full enrollment in the first quarter of 2017.

Two Pivotal Trials in Melanoma to Be Underway in 2017. In addition to the progress with IMblaze370, Roche has made it public that IMspire150 TRILOGY, which evaluates the combination of cobimetinib, atezolizumab, and vemurafenib in first-line BRAF V600 mutation-positive metastatic or unresectable locally advanced melanoma, enrolled its first patient in January 2017. IMspire170, a planned pivotal trial of cobimetinib and atezolizumab vs. pembrolizumab in first-line BRAF wild-type metastatic or unresectable locally advanced melanoma, is expected to enroll its first patient in the second quarter of this year.

Update on Dispute between Exelixis and Genentech. In January 2017, Exelixis announced that Genentech, a member of the Roche Group, had withdrawn its counterclaim against Exelixis in the ongoing JAMS arbitration concerning alleged breaches of the parties' collaboration agreement. Genentech had asserted a counterclaim for breach of contract, which sought monetary damages and interest related to cost allocations under the collaboration agreement. When notifying the arbitral panel, and Exelixis, of this unilateral action, Genentech further stated that it is changing the manner in which it allocates promotional expenses of the COTELLIC plus Zelboraf® (vemurafenib) combination therapy. Genentech's revised allocation applies retrospectively and prospectively and substantially reduces Exelixis' exposure to costs associated with promotion of the COTELLIC plus Zelboraf combination in the United States. Notwithstanding Genentech's change of approach, other significant issues remain in dispute between the parties. As a result, we will continue to press our position before the arbitral panel to obtain a just resolution of these claims. The ultimate outcome and timing of the arbitration is difficult to predict.

Corporate Highlights

Reduced Indebtedness Through Repayment of Silicon Valley Bank Loan. In late March 2017, Exelixis repaid all amounts outstanding under its term loan with Silicon Valley Bank initiated in 2010 and which was due for repayment on May 31, 2017. The payment included \$80.0 million in principal plus \$0.1 million in accrued and unpaid interest. The company also plans to repay the Deerfield Notes, a series of Convertible Secured Notes issued to entities associated with Deerfield Management Company, L.P. due July 1, 2018. Exelixis has designated the Deerfield Notes a Current Liability given its ability and intent to retire them on or about July 1, 2017, one year ahead of their maturity date. As of March 31, 2017, the carrying balance on the Deerfield Notes was \$113.9 million with the total of \$124.9 million due at maturity. Retiring the Deerfield Notes one year ahead of their maturity date will provide the company a savings of approximately \$12 million in interest expense, net of the termination fee.

Cabozantinib and Cobimetinib Data Presentations at the 2017 ASCO Annual Meeting. Exelixis-discovered compounds will be the subject of 13 presentations, including further analysis of the METEOR study in advanced RCC as well as updated results from the phase 1b combination trial of cabozantinib plus immunotherapy in genitourinary tumors. Additional cabozantinib data presentations will include results from trials in endometrial cancer and uterine carcinosarcoma. Cobimetinib data will include updates from the early stage combination trials of cobimetinib plus atezolizumab, and plus atezolizumab and vemurafenib, which have informed the design of several of Roche's ongoing or planned phase 3 pivotal trials.

2017 Financial Guidance

The company is reiterating its previously provided guidance that total costs and operating expenses for the full year will be between \$290 million and \$310 million. This guidance includes approximately \$25 million of non-cash costs and expenses related primarily to stock-based compensation expense.

First Quarter 2017 Financial Results

Total revenues for the quarter ended March 31, 2017 were \$80.9 million, compared to \$15.4 million for the comparable period in 2016. Total revenues include \$68.9 million of net product revenues compared to \$9.1 million for the comparable period in 2016. The increase in net product revenues primarily reflects the impact of the commercial launch of CABOMETYX in late April 2016. Total revenues also include \$12.0 million of collaboration revenues compared to \$6.3 million for the comparable period in 2016. Collaboration revenues for the quarter ended March 31, 2017 include \$4.5 million, \$2.7 million and \$2.3 million earned under our collaboration agreements with Ipsen, Takeda and Genentech, respectively, and \$2.5 million in contract revenues from a milestone payment received from BMS related to its ROR gamma program. In comparison, during the three months ended March 31, 2016, collaboration revenues include \$1.2 million and \$0.1 million in collaboration revenue under our collaboration agreements with Ipsen and Genentech, respectively, and \$5.0 million in contract revenues from a milestone payment received from Merck related to its worldwide license of our PI3K-delta program.

Research and development expenses for the quarter ended March 31, 2017 were \$23.2 million, compared to \$28.9 million for the comparable period in 2016. The decrease in research and development expenses were primarily a result of decreases in clinical trial costs for METEOR, the company's phase 3 trial in advanced RCC and share-based compensation; those decreases were partially offset by an increase 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 March 31, 2017 were \$34.3 million, compared to \$34.9 million for the comparable period in 2016. The decrease in selling, general and administrative expenses was primarily a result of decreases in marketing costs due to a decrease in losses under the collaboration agreement with Genentech and stock-based compensation; those decreases were almost entirely offset by increases in personnel expenses resulting from an increase in headcount connected with the build-out of the Exelixis U.S. commercial organization and an increase in legal costs.

Other expense, net for the quarter ended March 31, 2017 was a net expense of \$3.4 million compared to \$10.1 million for the comparable period in 2016. The decrease in other expense, net, was primarily due to a decrease in interest expenses as a result of the 2016 conversions and redemption of the 4.25 percent Convertible Subordinated Notes due 2019.

Net income for the quarter ended March 31, 2017 was \$16.7 million, or \$0.06 per share, basic, and \$0.05 per share, diluted, compared to a net loss of \$(59.2) million, or \$(0.26) per share, basic and diluted, for the comparable period in 2016. The decrease in net loss for the quarter ended March 31, 2017 was primarily due to the increase in net product and collaboration revenues and the decrease in operating and interest expenses.

Cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments totaled \$475.8 million at March 31, 2017, as compared to \$479.6 million at December 31, 2016.

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 March 31, 2017, December 30, 2016 and April 1, 2016 are indicated as being as of and for the periods ended March 31, 2017, December 31, 2016 and March 31, 2016, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for first quarter of 2017 and provide a general business update during a conference call beginning at 5:00 p.m. EDT/2:00 p.m. PDT today, Monday, May 1, 2017.

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 3901622 to join by phone.

A telephone replay will be available until 11:59 p.m. EDT on Wednesday, May 3, 2017. Access numbers for the telephone replay are: (855) 859-2056 (domestic) and (404) 537-3406 (international); the passcode is 3901622. 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 to improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the marketplace. Two are derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors: CABOMETRYX™ tablets approved for previously treated advanced kidney cancer and COMETRIQ® capsules approved for progressive, metastatic medullary thyroid cancer. The third product, COTELLIC®, is a formulation of cobimetinib, a selective inhibitor of MEK, is marketed under a collaboration with Genentech (a member of the Roche Group), and is approved as part of a combination regimen to treat advanced melanoma. Both cabozantinib and cobimetinib have shown potential in a variety of forms of cancer and are the subjects of broad clinical development programs. 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 maximizing the opportunity for cabozantinib and cobimetinib to help patients with cancer around the world; continued progress towards submission of a sNDA in the third quarter for cabozantinib as a treatment for previously untreated patients with advanced RCC based on the CABOSUN trial; continued co-promotion, with Genentech, of cobimetinib in combination with vemurafenib for melanoma in the U.S.; Genentech's continued expansion and advancement of its development program for cobimetinib and the planned initiation of its phase 3 pivotal trial of cobimetinib and atezolizumab vs. pembrolizumab in first-line BRAF wild-type advanced melanoma; Exelixis' efforts to build the company as a sustainable business, including repaying remaining debt this summer and assessing in-license opportunities and resuming drug discovery, in order to achieve growth and best in position to help patients and build long-term value; Exelixis' partnership with Takeda for Japanese commercialization and development of cabozantinib; Exelixis' collaborations with BMS and Roche for development of cabozantinib in combination with those companies' respective immunotherapy agents; Exelixis' expectation that the second interim analysis of the CELESTIAL trial in advanced HCC will be completed in the second half of 2017; Exelixis' intention to continue pressing its position in the arbitration against Genentech to obtain a just resolution; the likelihood that Exelixis-discovered compounds will be the subject of 13 presentations at the 2017 ASCO Annual Meeting; and Exelixis' guidance for 2017 total costs and operating expenses, including non-cash costs and expenses. Words such as "focused," "opportunity," "priority," "continue," "sustain," "potential," "planned," "intent," "anticipated," "will," "eligible," "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 CABOMETRYX, COMETRIQ, and COTELLIC and the availability of coverage and reimbursement for these products; the risk that unanticipated developments could adversely affect the commercialization of CABOMETRYX, COMETRIQ, and COTELLIC; Exelixis' dependence on its relationship with its collaboration partners, including, the level of their investment in the resources necessary to successfully commercialize cabozantinib and cobimetinib in the territories where they are approved; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; Exelixis' ability and the ability of its collaborators to conduct clinical trials of cabozantinib and cobimetinib both alone and in combination with other therapies sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib and cobimetinib, both alone and in

combination with other therapies, to demonstrate safety and efficacy in clinical testing; the level of 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' annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 27, 2017, 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 May 1, 2017. 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 March 31,	
	2017	2016
Revenues:		
Net product revenues	\$ 68,877	\$ 9,099
Collaboration revenues	12,010	6,328
Total revenues	<u>80,887</u>	<u>15,427</u>
Operating expenses:		
Cost of goods sold	3,203	685
Research and development	23,210	28,926
Selling, general and administrative	34,260	34,857
Restructuring charge	28	94
Total operating expenses	<u>60,701</u>	<u>64,562</u>
Income (loss) from operations	<u>20,186</u>	<u>(49,135)</u>
Other expense, net:		
Interest income and other, net	1,068	202
Interest expense	(4,420)	(10,290)
Total other expense, net	<u>(3,352)</u>	<u>(10,088)</u>
Income (loss) before income taxes	16,834	(59,223)
Income tax expense	134	—
Net income (loss)	<u>\$ 16,700</u>	<u>\$ (59,223)</u>
Net income (loss) per share, basic	\$ 0.06	\$ (0.26)
Net income (loss) per share, diluted	\$ 0.05	\$ (0.26)
Shares used in computing basic net income (loss) per share	290,870	228,304
Shares used in computing diluted net income (loss) per share	309,535	228,304

EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)
(unaudited)

	March 31,	December 31,
	2017	2016 (1)
Cash and investments (2)	\$ 475,774	\$ 479,554
Working capital	\$ 265,663	\$ 200,215
Total assets	\$ 586,980	\$ 595,739
Total stockholders' equity	\$ 119,750	\$ 89,318

(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 as of both March 31, 2017 and December 31, 2016.



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