



Exelixis Announces Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

February 27, 2017

- Cabozantinib Franchise Net Product Revenues of \$51.9 million for the Fourth Quarter 2016, \$135.4 million for the Full Year 2016 -

- Total Revenues of \$77.6 million for the Fourth Quarter 2016, \$191.5 million for the Full Year 2016 -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 27, 2017-- Exelixis, Inc. (Nasdaq:EXEL) today reported financial results for the fourth quarter and full year of 2016 and provided an update on progress toward delivering upon its key corporate objectives, as well as commercial and clinical development milestones.

Exelixis is focused on maximizing the opportunity for its two internally-discovered compounds, cabozantinib and cobimetinib, each of which has the potential to help patients around the world fighting a variety of cancers. The company's most immediate priority is continuing to execute 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 \$44.7 million and \$93.5 million in net product revenue during the fourth quarter and full year of 2016, respectively. COMETRIQ® (cabozantinib) capsules for the treatment of medullary thyroid cancer generated an additional \$7.2 million and \$41.9 million in net product revenue during the fourth quarter and full year of 2016, respectively. In addition, Exelixis is preparing a regulatory filing for cabozantinib as a treatment for previously-untreated patients with advanced RCC based on the positive data from the CABOSUN randomized phase 2 trial. Exelixis and its partner Genentech, a member of the Roche Group, are co-promoting Cotellic® (cobimetinib) in the United States, while Genentech continues to advance the cobimetinib clinical development program, which now includes three ongoing or planned phase 3 pivotal trials of combination regimens including cobimetinib for forms of colorectal cancer and advanced melanoma.

"2016 marked an inflection point for Exelixis, with the U.S. approval and launch of CABOMETYX, and the emergence of key data sets that have supported a significantly expanded late-stage clinical development program for cobimetinib. At the same time, we secured important partnerships and collaborations that will further advance the cabozantinib franchise on a global basis and improved our balance sheet, providing strength and flexibility as we move forward," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis.

"We started 2017 in a strong financial position with a focus on driving the business to generate free cash to reinvest in our pipeline. We are making progress towards a U.S. regulatory filing based on the CABOSUN results, targeted for the third quarter of this year, and have recently announced collaborations focused on conducting late-stage clinical trials of cabozantinib in combination with leading immunotherapies. Separately, our partner Genentech continues to expand its late-stage clinical development program for cobimetinib in areas of considerable therapeutic and commercial potential. The robust clinical development programs for both cabozantinib and cobimetinib form a solid foundation to build on in the year ahead as we and our partners work to improve cancer care for patients around the world."

Cabozantinib Highlights

Strong Growth in Cabozantinib Franchise Net Revenues. Cabozantinib generated \$51.9 million in net product revenue during the fourth quarter of 2016, an increase of 21 percent from the third quarter of 2016. Full year 2016 net product revenue was \$135.4 million, an increase of 296 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.

Presented Positive Results from Phase 2 CABOSUN Trial in Advanced RCC. At the European Society for Medical Oncology (ESMO) Congress in October 2016, 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 (The Alliance) with support from the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP).

Advanced Filing Plans for Cabozantinib in Previously Untreated Advanced RCC. In the fourth quarter 2016, the transfer of the CABOSUN clinical database from The Alliance to Exelixis was completed, and Exelixis is preparing a Supplemental New Drug Application, which is targeted for submission in the third quarter of 2017.

Phase 1 Trial Results for Cabozantinib in Combination with Nivolumab in Advanced Genitourinary Tumors. Also at the ESMO 2016 Congress, encouraging results were presented from Part 1 of the two part NCI-CTEP-sponsored phase 1 trial of cabozantinib in combination with nivolumab in patients with previously treated genitourinary tumors. Expansion cohorts assessing cabozantinib and nivolumab, including patients with bladder, renal, and rare genitourinary cancers, are also currently being accrued.

At the ASCO Genitourinary Cancers Symposium in February 2017, investigators presented new data from Part 1 as well as Part 2 of the trial, which

adds ipilimumab to the combination regimen of cabozantinib and nivolumab.

Collaborations for Late-Stage Development of Cabozantinib in Combination with Immunotherapies. After the year ended, Exelixis announced agreements with Bristol-Myers Squibb (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. 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 testing of cabozantinib in combination with Tecentriq® (atezolizumab), an anti-PD-L1 antibody, in patients with advanced RCC or bladder cancer.

New and Amended Partnerships to Support the Global Cabozantinib Franchise. On December 21, 2016, Exelixis and Ipsen announced an amendment to their exclusive collaboration and licensing agreement for the commercialization and continued development of cabozantinib, to include commercialization rights in Canada for Ipsen. Exelixis received a \$10.0 million upfront payment and is eligible to receive regulatory milestones for the approvals of cabozantinib in Canada for advanced RCC after prior treatment, for first-line advanced RCC, and advanced HCC, as well as additional regulatory milestones for potential further indications. In line with the prior transaction between the parties, the agreement also includes commercial milestones and provides for Exelixis to receive tiered royalties on Ipsen's net sales of cabozantinib in Canada.

After the year ended, 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 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 and 100 percent of costs associated with the cabozantinib development activities that are exclusively for the benefit of Japan.

Cobimetinib Highlights

Results Presented at ESMO 2016 from Cobimetinib Combination Trials Support Further Advancement. Cobimetinib, the Exelixis-discovered MEK inhibitor that is the subject of a worldwide collaboration with Genentech, a member of the Roche Group, was featured in 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. These results provided the rationale for the Roche-sponsored phase 3 pivotal trial, IMspire150 TRILOGY, which began enrolling patients in January 2017.

Investigators also presented updated results from the phase 1 trial of cobimetinib plus atezolizumab in advanced colorectal cancer that provide the rationale for IMblaze370 (formerly known as 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.

Presentation of Cobimetinib Combination Therapy Data at the Society for Melanoma Research 2016 Congress. On November 7, 2016, Exelixis announced the presentation of data from the metastatic melanoma cohort of a phase 1b dose escalation trial of cobimetinib and atezolizumab in patients with solid tumors. Data from this trial will form the basis of a Genentech-sponsored phase 3 pivotal trial of the combination in patients with previously untreated BRAF wild-type advanced melanoma, which is also expected to start this year.

Update on Dispute between Exelixis and Genentech. Since the conclusion of the fourth quarter, Exelixis announced that Genentech, Inc., 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.

2017 Financial Guidance

The company is providing 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.

Fourth Quarter and Full Year 2016 Financial Results

Total revenues for the quarter ended December 31, 2016 were \$77.6 million, compared to \$9.9 million for the comparable period in 2015. Total revenues for the year ended December 31, 2016 were \$191.5 million, compared to \$37.2 million for the comparable period in 2015.

Total revenues for the quarter ended December 31, 2016 include \$51.9 million of net product revenues compared to \$9.9 million for the comparable period in 2015. Net product revenues for the year ended December 31, 2016 were \$135.4 million, compared to \$34.2 million for the comparable period in 2015. The increase in net product revenues for both the quarter and year ended December 31, 2016, as compared to the same periods in 2015, primarily reflects the impact of the commercial launch of CABOMETYX in late April 2016.

Total revenues for the quarter ended December 31, 2016 also include two \$10.0 million milestones achieved for the first commercial sales of CABOMETYX by Ipsen in Germany and the United Kingdom. Total revenues for the year ended December 31, 2016 also include the recognition of \$20.0 million of revenue for milestones from two of our collaboration partners, Daiichi Sankyo and Merck. Total revenues for the quarter and year ended December 31, 2016 also include \$1.0 million and \$2.8 million, respectively, of royalty revenues from Ipsen and Roche and \$4.7 million and \$13.3 million, respectively, of license revenues from Ipsen.

In comparison, during the year ended December 31, 2015, we recognized \$3.0 million of contract revenues for a milestone payment received from

Merck.

Research and development expenses for the quarter ended December 31, 2016 were \$23.8 million, compared to \$23.5 million for the comparable period in 2015. Research and development expenses for the year ended December 31, 2016 were \$96.0 million, compared to \$96.4 million for the comparable period in 2015. For both the quarter and year-ended December 31, 2016 as compared to the same periods in 2015, decreases in share-based compensation and the allocation of general corporate costs were 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. For the year-ended December 31, 2016 as compared to the same period in 2015, there were also decreases in clinical trial costs for METEOR, the Company's phase 3 trial in advanced RCC.

Selling, general and administrative expenses for the quarter ended December 31, 2016 were \$13.0 million, compared to \$17.1 million for the comparable period in 2015. Selling, general and administrative expenses for the year ended December 31, 2016 were \$116.1 million, compared to \$57.3 million for the comparable period in 2015. For both the quarter and year-ended December 31, 2016 as compared to the same periods in 2015, there were increases in personnel related expenses resulting from an increase in headcount connected with the build-out of the Exelixis U.S. commercial organization and outside services to support the launch and commercialization of CABOMETYX. These increases were offset by a decrease in marketing costs related to losses on our collaboration with Genentech.

As described above, in December 2016 Genentech stated that it changed, both retroactively and prospectively, the manner in which it allocates promotional expenses of the Cotellic plus Zelboraf combination therapy. As a result, Exelixis is relieved of \$18.7 million of disputed costs previously recorded by Exelixis, and Exelixis has invoiced Genentech for expenses, with interest, that Exelixis had previously paid. Accordingly, during the quarter ended December 31, 2016, we offset selling, general and administrative expenses for a \$23.1 million recovery of net losses, which had been recorded from 2013 through September 30, 2016, including \$13.3 million for losses that we had recognized and recorded prior to 2016. During the quarter and year ended December 31, 2016, we also recognized a net gain of \$0.6 million and a net loss of \$4.5 million, respectively, for current U.S. activities in those periods under the collaboration agreement as computed under Genentech's revised cost allocation approach.

Other expense, net for the quarter ended December 31, 2016 was a net expense of (\$3.8) million compared to (\$9.9) million for the comparable period in 2015. Other expense, net for the year ended December 31, 2016 was a net expense of (\$42.1) million compared to (\$40.3) million for the comparable period in 2015. The decrease in other expense, net for the quarter ended December 31, 2016 as compared to 2015 was primarily due to the reduction in interest expense as a result of the conversion and redemption of \$287.5 million in aggregate principal amount of our 4.25% Convertible Senior Subordinated Notes due 2019 (2019 Notes). For the year ended December 31, 2016, the reduction in interest expense was offset by \$13.9 million of loss associated with the conversion of our 2019 Notes for 54,009,279 shares of our common stock.

Net income (loss) for the quarter ended December 31, 2016 was net income of \$35.1 million, or \$0.12 per share, basic and fully diluted, compared to a net loss (\$41.6) million, or (\$0.18) per share, basic and fully diluted, for the comparable period in 2015. Net loss for the year ended December 31, 2016 was a net loss (\$70.2) million, or (\$0.28) per share, basic and fully diluted, compared to a net loss (\$161.7) million, or (\$0.77) per share, basic and fully diluted, for the comparable period in 2015. The decrease in net loss for the quarter and year ended December 31, 2016 was primarily due to increases in net product revenues; increases in collaboration revenues; the recovery of net losses previously recorded under our collaboration agreement with Genentech; and a decrease in interest expense; partially offset by increases in personnel expenses associated with the increase in headcount connected with the build-out of the Exelixis U.S. commercial and medical affairs organizations and other costs associated with the launch of CABOMETYX. For the year ended December 31, 2016, the decrease in net loss was also partially offset by the loss associated with the conversion of the 2019 Notes.

Cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments totaled \$479.6 million at December 31, 2016 as compared to \$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 December 30, 2016 and January 1, 2016 are indicated as being as of and for the periods ended December 31, 2016 and December 31, 2015, respectively.

Conference Call and Webcast

Exelixis management will discuss the company's financial results for the fourth quarter and full year 2016 and provide a general business update during a conference call beginning at 5:00 p.m. EST/2:00 p.m. PST today, Monday, February 27, 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 60535366 to join by phone.

A telephone replay will be available until 11:59 p.m. EST on Wednesday, March 1, 2017. Access numbers for the telephone replay are: (855) 859-2056 (domestic) and (404) 537-3406 (international); the passcode is 60535366. 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: CABOMETYX™ 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; the potential of cabozantinib and cobimetinib to help patients around the world fighting a variety of cancers; the company's immediate priority to continue to execute on the U.S. launch of CABOMETYX tablets as a treatment for patients with advanced RCC; Genentech's continued expansion and advancement of its late stage clinical development program for cobimetinib in areas of considerable therapeutic and commercial potential, including a plan to initiate a phase 3 pivotal trial for advanced melanoma; Exelixis' focus on driving the business to generate free cash to reinvest in its pipeline; Exelixis' plan to target a U.S. regulatory filing based on the CABOSUN results in the third quarter of 2017; Exelixis' and BMS' intent to collaborate on the evaluation of cabozantinib in combination with Opdivo alone or in combination with Yervoy in a phase 3 trial in first-line RCC, and potentially in other tumor types, including HCC and bladder cancer; Exelixis' expectation that studies under the collaboration with BMS will begin in 2017; Exelixis' and Roche's plan to collaborate to initiate testing of cabozantinib in combination with atezolizumab in patients with advanced RCC or bladder cancer; Exelixis' eligibility to receive regulatory milestones for approvals of cabozantinib in Canada from Ipsen, as well as commercial milestones and royalties on Ipsen's net sales of cabozantinib in Canada; Exelixis' eligibility to receive development, regulatory and first-sales milestones from Takeda, as well as royalties on sales by Takeda; Exelixis' guidance for 2017 total costs and operating expenses, including non-cash costs and expenses; and Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Words such as "focused," "opportunity," "potential," "priority," "planned," "continue," "intent," "targeted," "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 CABOMETYX and COMETRIQ and the availability of coverage and reimbursement for CABOMETYX and COMETRIQ; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX or COMETRIQ; Exelixis' dependence on its relationship with its cabozantinib collaboration partners, including, the level of their investment in the resources necessary to successfully commercialize cabozantinib in the territories where it is approved; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; Exelixis' ability and the ability of its collaborators to conduct clinical trials of cabozantinib both alone and in combination with other therapies sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib, 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' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 3, 2016, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' annual report on Form 10-K expected to be filed with the SEC on February 27, 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 December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Revenues:				
Net product revenues	\$ 51,916	\$ 9,924	\$ 135,375	\$ 34,158
Collaboration revenues	25,665	14	56,079	3,014
Total revenues	77,581	9,938	191,454	37,172
Operating expenses:				
Cost of goods sold	1,852	1,023	6,552	3,895
Research and development	23,801	23,472	95,967	96,351
Selling, general and administrative	13,002	17,143	116,145	57,305
Restructuring (recovery) charge	43	(100)	914	1,042
Total operating expenses	38,698	41,538	219,578	158,593
Income (loss) from operations	38,883	(31,600)	(28,124)	(121,421)
Other expense, net:				
Interest income and other, net	853	266	4,863	412
Interest expense	(4,485)	(10,179)	(33,060)	(40,680)
Loss on extinguishment of debt	(128)	—	(13,901)	—
Total other expense, net	(3,760)	(9,913)	(42,098)	(40,268)
Income (loss) before income taxes	35,123	(41,513)	(70,222)	(161,689)
Income tax provision	—	55	—	55
Net income (loss)	\$ 35,123	\$ (41,568)	\$ (70,222)	\$ (161,744)

Net income (loss) per share, basic and diluted	\$ 0.12	\$ (0.18)	\$ (0.28)	\$ (0.77)
Shares used in computing basic net income (loss) per share	288,158	227,449		250,531		209,227	
Shares used in computing diluted net income (loss) per share	301,324	227,449		250,531		209,227	

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

	December 31, 2016	December 31, 2015 ⁽¹⁾
	(unaudited)	
Cash and investments ⁽²⁾	\$ 479,554	\$ 253,310
Working capital	\$ 200,215	\$ 126,414
Total assets	\$ 597,541	\$ 332,342
Total stockholders' equity (deficit)	\$ 89,318	\$ (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.

(2) Long-term restricted cash and investments totaled \$4.2 million and \$2.7 million as of December 31, 2016 and December 31, 2015, respectively.

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Source: Exelixis, Inc.

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