



## Exelixis Announces First Quarter 2016 Financial Results and Provides Corporate Update

May 4, 2016

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

SOUTH SAN FRANCISCO--(BUSINESS WIRE)--May 4, 2016-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2016 and provided an update on progress toward delivering upon its key 2016 corporate objectives and clinical development milestones.

### **Corporate Updates and Key Priorities for 2016**

On April 25, 2016, the U.S. Food and Drug Administration (FDA) approved CABOMETRYX™ (cabozantinib) tablets as a treatment for patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. With approval granted, Exelixis is highly focused on the U.S. commercial launch for CABOMETRYX. CABOMETRYX was shipped to wholesalers and pharmacies within three days of approval, with the first prescription filled on April 28, 2016. The European Medicines Agency (EMA) is reviewing the company's Marketing Authorization Application (MAA) for cabozantinib for advanced RCC; assuming approval, the product would be marketed in the EU by the company's corporate partner, Ipsen Pharma SAS (Ipsen).

Exelixis continues to work with its partner Genentech, a member of the Roche Group, to co-promote COTELLIC™ (cobimetinib) in the United States as a treatment for patients with BRAF V600E or V600K mutation-positive advanced melanoma, in combination with vemurafenib, also known as Zelboraf®. COTELLIC is also approved in multiple other territories including the EU and Canada.

### **Corporate Highlights**

**Exclusive Licensing Agreement with Ipsen for Cabozantinib in Regions Outside the United States, Canada and Japan.** On February 29, 2016, Exelixis announced an exclusive licensing agreement with Ipsen for the commercialization and further development of cabozantinib for its current and potential future indications, including COMETRIQ® (cabozantinib) capsules, outside the United States, Canada and Japan. Pursuant to the parties' agreement, Exelixis received an upfront payment from Ipsen of \$200.0 million in the first quarter of 2016. The company is also eligible to receive regulatory milestones, including \$60.0 million upon the approval of cabozantinib in Europe for advanced RCC and \$50.0 million upon the filing and approval of cabozantinib in Europe for advanced hepatocellular carcinoma (HCC), as well as additional development and regulatory milestones for potential further indications. The agreement includes up to \$545.0 million of potential commercial milestones and provides for Exelixis to receive tiered royalties up to 26% on Ipsen's net sales of cabozantinib in its territories. Exelixis and Ipsen have agreed to collaborate on the global development of cabozantinib for current and potential future indications as well.

### **Cabozantinib Highlights**

**FDA Approval of CABOMETRYX, the Third Approved Medicine to Have Been Discovered by Exelixis.** On April 25, 2016, the U.S. FDA approved CABOMETRYX for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy. CABOMETRYX is the first therapy to demonstrate robust and clinically meaningful improvements in all three key efficacy parameters - overall survival (OS), progression-free survival (PFS) and objective response rate (ORR) - in a phase 3 trial (METEOR) for patients with advanced RCC.

The CABOMETRYX label includes data from the second interim analysis of the METEOR trial's OS secondary endpoint. In February 2016, Exelixis announced that CABOMETRYX demonstrated a highly statistically significant and clinically meaningful improvement in OS as compared to everolimus. These results have been accepted as an oral presentation at the American Society of Clinical Oncology's (ASCO) 2016 Annual Meeting, June 3-7, in Chicago, and will be presented in detail on Sunday, June 5, during the Oral Abstract Session: Genitourinary (Nonprostate) Cancer, 10:12 - 10:24 a.m.

**Progress on EU Regulatory Filing for Cabozantinib in Advanced RCC.** In January 2016, Exelixis submitted, and the EMA subsequently validated, the company's regulatory application for cabozantinib as a treatment for patients with advanced RCC who have received one prior therapy. In validating the MAA, the EMA granted accelerated assessment, making the application eligible for a shortened 150-day review excluding clock-stops when information is requested from Exelixis. Exelixis intends to transfer the MAA to Ipsen later this year.

**Continued Enrollment in CELESTIAL; Data Anticipated in 2017.** Exelixis continues to make progress with enrollment of CELESTIAL, the phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC who have previously been treated with sorafenib. Initiated in September 2013, the trial is designed to enroll 760 patients at approximately 200 sites. Patients are being randomized 2:1 to receive 60 mg of cabozantinib daily or placebo. The primary endpoint for CELESTIAL is OS, and the secondary endpoints include PFS and ORR. Exelixis continues to anticipate top-line results from CELESTIAL in 2017. At this time, there is no approved treatment for HCC patients who progress following sorafenib treatment, the current standard of care.

**Broad Cabozantinib Development Program Updates.** While Exelixis pursues cabozantinib's late-stage development in advanced RCC and advanced HCC, earlier-stage investigation of the compound 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. Through these two programs, there are more than 45 ongoing or planned studies including trials in advanced RCC, bladder cancer, colorectal cancer, non-small cell lung cancer, and endometrial cancer.

**Cabozantinib, Cobimetinib and XL888 Data Presentations at ASCO 2016.** Exelixis-discovered compounds will be the subject of 18 presentations at the meeting. In addition to the OS results from the METEOR study in advanced RCC, there will be a poster presentation from the same trial on outcomes based on prior therapy. Additional presentations will highlight results from early and mid-stage trials of cabozantinib in other disease settings, including metastatic colorectal cancer, endometrial cancer and metastatic urothelial carcinomas. Cobimetinib data will include updates on

combination trials of the compound in metastatic melanoma, triple-negative breast cancer, and colorectal cancer. Exelixis will also host an investor/analyst briefing at the meeting on Sunday, June 5, 2016; see the Investors & Media section of [www.exelixis.com](http://www.exelixis.com) for more details when available.

### **Cobimetinib Highlights**

**Additional Regulatory Approvals for COTELLIC.** In April and May 2016, Australia's Therapeutic Goods Administration and Brazil's ANVISA, respectively, approved COTELLIC for use in combination with Zelboraf for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation. As previously announced, in February 2016 Health Canada approved COTELLIC in combination with Zelboraf for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

### **2016 Financial Guidance**

The Company is maintaining its guidance that operating expenses for the full year 2016 will be between \$240 million and \$270 million, including approximately \$30 million of non-cash items primarily related to stock-based compensation expense.

"The first quarter of 2016, and the time period following it, was marked by important advances not only for our company, but for the patients we serve," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Most notably, just a little over a week ago we announced that the FDA approved CABOMETYX for advanced RCC, a major milestone for the company. We are especially pleased that the label includes the robust overall survival data from the METEOR trial. CABOMETYX is now the first and only therapy to have demonstrated improvements in the three key efficacy parameters in a phase 3 trial of advanced renal cell carcinoma, one of the most common forms of cancer for men and women in the United States. We are moving quickly to introduce this new and important medicine to the medical community, with our experienced U.S. commercial team already in the field and meeting with healthcare providers. With our partner Ipsen, we are also well positioned to advance the process of seeking approval and potentially commercializing CABOMETYX in markets beyond the U.S., Canada and Japan."

### **First Quarter 2016 Financial Results**

**Net revenues** for the quarter ended March 31, 2016 were \$15.4 million, compared to \$9.4 million for the comparable period in 2015. Net revenues for the first quarter of 2016 consisted of \$9.1 million of net product revenue related to the sale of COMETRIQ, \$5.0 million of contract revenues for a milestone earned from Merck in the first quarter of 2016 related to their worldwide license of our PI3K-delta program and \$1.2 million of license revenues recognized from the upfront payment we received from Ipsen under our collaboration and license agreement.

**Research and development expenses** for the quarter ended March 31, 2016 were \$28.9 million, compared to \$22.3 million for the comparable period in 2015. The increase was primarily related to an increase in stock-based compensation expense for performance-based stock-options and an annual bonus to our employees in the form of fully-vested restricted stock units, an increase in personnel related expenses resulting from an increase in headcount and an increase in consulting and outside services for medical affairs and drug safety.

**Selling, general and administrative expenses** for the quarter ended March 31, 2016 were \$34.9 million, compared to \$9.5 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, predominantly connected to the expansion of our U.S. sales force, higher marketing expenses which includes a portion of commercialization expenses from COTELLIC under our collaboration agreement with Genentech, consulting and outside services expenses which includes an accrual for the estimated termination fee due to Sobi, and stock-based compensation expense for performance-based stock-options and an annual bonus to our employees in the form of fully-vested restricted stock units.

**Other income (expense), net** for the quarter ended March 31, 2016 was a net expense of (\$12.2) million compared to (\$12.4) million for the comparable period in 2015. The net expense is comprised primarily of interest expense which includes \$7.2 million of non-cash expense related to the accretion of the discounts on both the 4.25% Convertible Senior Subordinated Notes due 2019 and the Company's indebtedness under our Secured Convertible Notes due June 2018 held by entities associated with Deerfield for the quarter ended March 31, 2016, as compared to \$7.7 million for the comparable period in 2015.

**Net loss** for the quarter ended March 31, 2016 was (\$61.3) million, or (\$0.27) per share, basic, compared to (\$35.2) million, or (\$0.18) per share, basic, for the comparable period in 2015. The increased net loss for the quarter was primarily due to increases in selling, general and administrative expenses and research and development expenses, partially offset by an increase in net revenues.

**Cash** and cash equivalents, short- and long-term investments and long-term restricted cash and investments totaled \$407.6 million at March 31, 2016, which increased from \$253.3 million at December 31, 2015 as a result of the \$200.0 million upfront payment we received from Ipsen in connection with our February 29, 2016 licensing agreement.

### **Basis of Presentation**

Exelixis adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31<sup>st</sup>. For convenience, references in this press release as of and for the fiscal periods ended April 1, 2016, January 1, 2016 and March 28, 2015 are indicated as being as of and for the periods ended March 31, 2016, December 31, 2015 and March 31, 2015, respectively.

### **Conference Call and Webcast**

Exelixis management will discuss the company's financial results for the first 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, Wednesday, May 4, 2016. To listen to a live webcast of the conference call, visit the Event Calendar page under Investors & Media at [www.exelixis.com](http://www.exelixis.com). Alternatively, participants may dial (855) 793-2457 (domestic) or (631) 485-4921 (international) and provide the conference call passcode 82069908 to join by phone.

An archived replay of the webcast will be available on the Event Calendar page under Investors & Media at [www.exelixis.com](http://www.exelixis.com) for one year. An audio-only phone replay will be available until 11:59 p.m. EDT on May 6, 2016. Access numbers for the phone replay are: (855) 859-2056 (domestic) and (404) 537-3406 (international); the passcode is 82069908.

### **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 CABOMETYX™ tablets (U.S.) 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](http://www.exelixis.com) or follow [@ExelixisInc](https://twitter.com/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. commercial launch for CABOMETYX; the plan that, assuming approval of cabozantinib for advanced RCC by the EMA, the product would be marketed in the EU by Ipsen; Exelixis' plan to continue to work with its partner Genentech to co-promote COTELLIC in the United States; the business and financial terms of the collaboration agreement for cabozantinib with Ipsen, including, the division of commercialization rights, development plans and Exelixis' eligibility to receive regulatory and commercial milestones and royalties; future data presentations for cabozantinib, cobimetinib and XL888 at the ASCO 2016 Annual Meeting; the eligibility for an expedited review of Exelixis' MAA for cabozantinib in advanced RCC by the EMA; Exelixis' intention to transfer the MAA to Ipsen later this year; the status of enrollment progress for and the timing of anticipated top-line results from CELESTIAL; the continued development of cabozantinib through Exelixis' collaboration with NCI-CTEP and its ongoing IST program; Exelixis' anticipated operating expenses for 2016, including non-cash items; Exelixis' belief that the company is well-positioned to advance the process of seeking approval and potentially commercializing CABOMETYX in markets beyond the U.S., Canada and Japan; 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," "assuming," "would," "eligible," "potential," "future," "will," "intend," "continues," "anticipate," "planned," "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; Exelixis' ability to judge the proper size and level of experience of the commercialization teams required to support the launch of cabozantinib for advanced RCC in the U.S.; 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 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; the availability of data at the referenced times; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the sufficiency of Exelixis' resources; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX or COMETRIQ; 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 29, 2016, 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 4, 2016. 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 and COMETRIQ are registered U.S. trademarks, and CABOMETYX and COTELLIC are U.S. trademarks.*

## **EXELIXIS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share data)

(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenues:		
Net product revenues	\$ 9,099	\$ 9,388
License and contract revenues	6,328	—
Total revenues	<u>15,427</u>	<u>9,388</u>
Operating expenses:		
Cost of goods sold	685	766
Research and development	28,926	22,282
Selling, general and administrative	34,857	9,531
Restructuring charge	94	(431)
Total operating expenses	<u>64,562</u>	<u>32,148</u>
Loss from operations	<u>(49,135)</u>	<u>(22,760)</u>
Other income (expense), net:		
Interest income and other, net	202	(7)

Interest expense	(12,414)	(12,403)
Total other income (expense), net	(12,212)	(12,410)
Net loss	<u>\$ (61,347)</u>	<u>\$ (35,170)</u>
Net loss per share, basic and diluted	\$ (0.27)	\$ (0.18)
Shares used in computing basic and diluted net loss per share	228,304	195,904

**EXELIXIS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEET DATA**

(in thousands)

	<b>March 31, 2016</b>	<b>December 31, 2015 (1)</b>
	(unaudited)	<u>2015 (1)</u>
Cash and investments (2)	\$ 407,617	\$ 253,310
Working capital	\$ 238,401	\$ 126,414
Total assets	\$ 492,533	\$ 332,342
Total stockholders' deficit	\$ (155,954)	\$ (104,304)

(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 \$2.7 million as of March 31, 2016 and December 31, 2015.



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*Exelixis, Inc.*

*Chris Senner, 650-837-7240*

*Chief Financial Officer*

[csenner@exelixis.com](mailto:csenner@exelixis.com)

*Susan Hubbard, 650-837-8194*

*Investor Relations*

*& Corporate Communications*

[shubbard@exelixis.com](mailto:shubbard@exelixis.com)