



## Exelixis Announces First Quarter 2018 Financial Results and Provides Corporate Update

May 2, 2018

- **Total Revenues of \$212.3 million** -

- **Cabozantinib Franchise Net Product Revenues of \$134.3 million** -

- **Net Income of \$115.9 million, Diluted EPS of \$0.37** -

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

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 2, 2018-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2018 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

"In the first quarter of 2018, Exelixis continued to make significant progress in the ongoing commercialization of CABOMETYX® (cabozantinib) for advanced renal cell carcinoma. Following FDA approval for its expanded indication in advanced first-line renal cell carcinoma, our team immediately began promoting CABOMETYX across all lines of therapy for this patient population, resulting in further uptake from prescribers at both major academic institutions and in the community setting," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "The resulting growth in U.S. sales, as well as the increasing collaboration revenues from our various partners, were important contributors to our strong financial performance during the quarter, leading to net income of \$115.9 million or \$0.37 per share on a fully diluted basis."

Dr. Morrissey continued: "From its initial approval for a rare disease indication five years ago, cabozantinib has grown to become an oncology franchise with the potential for global impact. We and our collaboration partners are committed to maximizing its opportunity to help patients across multiple tumor types. This now includes our recent regulatory submissions for previously treated advanced hepatocellular carcinoma, an aggressive cancer with worldwide relevance. Our efforts in liver cancer, as well as our plans to start additional phase 3 trials in other forms of cancer later this year, are each reflective of the Exelixis corporate mission to help patients with cancer recover stronger and live longer."

### First Quarter 2018 Financial Results

**Total revenues** for the quarter ended March 31, 2018 were \$212.3 million, compared to \$80.9 million for the comparable period in 2017.

Total revenues include net product revenues of \$134.3 million for the quarter ended March 31, 2018, compared to \$68.9 million for the comparable period in 2017. The increase in net product revenues reflects the growth of our second and later-line advanced renal cell carcinoma (RCC) business and the impact of additional sales following the U.S. Food and Drug Administration's (FDA) approval in December 2017 of the expanded indication for CABOMETYX, which now encompass all patients with advanced RCC.

Total revenues also include collaboration revenues of \$78.1 million for the quarter ended March 31, 2018 compared to \$12.0 million for the comparable period in 2017. The increase in collaboration revenues for the quarter ended March 31, 2018 was primarily the result of recording \$45.8 million in revenue for a \$50.0 million milestone from Ipsen Pharma SAS (Ipsen) we expect to earn in the second quarter of 2018 for the approval of cabozantinib for the first-line treatment of advanced RCC by the European Commission (EC). The determination to recognize the \$45.8 million in revenue was made following the Committee for Medicinal Products for Human Use's (CHMP) positive opinion of cabozantinib for the first-line treatment of advanced RCC. The increase in collaboration revenues was also a result of a \$20.0 million milestone from our collaboration partner Daiichi Sankyo Company, Limited (Daiichi Sankyo), which was earned as a result of Daiichi Sankyo's submission of a regulatory application to the Japanese Pharmaceutical and Medical Devices Agency for esaxerenone (CS-3150) as a treatment for patients with essential hypertension. These increases were partially offset by a decrease in the recognition of deferred revenue due to our adoption of Accounting Standards Update No. 2014-09 *Revenue from Contracts with Customers (Accounting Standards Codification Topic 606)* on January 1, 2018. As a result, \$258.5 million was recorded in stockholders' equity relating primarily to a reduction in the remaining unrecognized upfront and non-substantive milestone payments that had been received from our collaboration partners and was included in deferred revenue at December 31, 2017. For more information on our adoption of the new revenue standard, see "Note 1. Organization and Summary of Significant Accounting Policies - Revenue" contained in Part I, Item 1 of Exelixis' Quarterly Report on Form 10-Q expected to be filed with the Securities and Exchange Commission (SEC) on May 2, 2018.

**Research and development expenses** for the quarter ended March 31, 2018 were \$37.8 million, compared to \$23.2 million for the comparable period in 2017. The increase in research and development expenses was primarily related to an increase in personnel-related expenses resulting from an increase in headcount in support of our development and discovery efforts and an increase in clinical trial costs. Clinical trial costs increased primarily due to start-up costs associated with CheckMate 9ER, an ongoing phase 3 pivotal trial of cabozantinib plus immunotherapy in patients with previously untreated RCC that is being conducted with Bristol-Myers Squibb Company, and start-up costs associated with our phase 1b trial of cabozantinib and atezolizumab in locally advanced or metastatic solid tumors; those increases were partially offset by decreases in costs related to METEOR, our completed phase 3 pivotal trial comparing CABOMETYX to everolimus in patients with advanced RCC. Research and development expenses for the quarter ended March 31, 2018 also included a \$3.0 million upfront payment for our exclusive collaboration and license agreement with StemSynergy Therapeutics, Inc. (StemSynergy).

**Selling, general and administrative expenses** for the quarter ended March 31, 2018 were \$52.6 million, compared to \$34.3 million for the comparable period in 2017. The increase in selling, general and administrative expenses was primarily a result of increases in corporate giving, personnel expenses and marketing activities. The increase in personnel expense resulted from an increase in general and administrative headcount to support the company's commercial and research and development organizations.

**Net income** for the quarter ended March 31, 2018 was \$115.9 million, or \$0.39 per share, basic and \$0.37 per share, diluted, compared to a \$16.7 million, or \$0.06 per share, basic and \$0.05 per share diluted, for the comparable period in 2017. The increase in net income was primarily the result of increases in net product revenues and collaboration revenues, which was partially offset by the increases in research and development and selling, general and administrative expenses.

**Cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments** totaled \$525.6 million at March 31, 2018, as compared to \$457.2 million at December 31, 2017.

## 2018 Financial Guidance

The company is maintaining its guidance that total costs and operating expenses for the full year will be between \$430 million and \$460 million. This guidance includes approximately \$50 million of non-cash costs and expenses related primarily to stock-based compensation expense.

## Cabozantinib Highlights

**Strong Growth in Cabozantinib Franchise Net Revenues.** Cabozantinib generated \$134.3 million in net product revenues during the first quarter of 2018, an increase of 95 percent year-over-year. During the first quarter of 2018, CABOMETYX generated \$128.9 million in net product revenues and COMETRIQ® (cabozantinib) capsules for the treatment of patients with progressive, metastatic medullary thyroid cancer generated an additional \$5.3 million in net product revenues.

**Amendment to Clinical Research Protocol for Phase 1b Trial of Cabozantinib in Combination with Atezolizumab in Patients with Locally Advanced or Metastatic Solid Tumors.** In January, Exelixis announced an amendment to the protocol for the phase 1b trial of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. The amendment added four new expansion cohorts to the trial, which now includes patients with non-small cell lung cancer and castration-resistant prostate cancer, in addition to previously included patients with RCC and urothelial carcinoma (UC). The primary objective in the expansion stage of this trial remains to determine the objective response rate in each cohort.

**Cabozantinib Data at the ASCO 2018 Genitourinary Cancers Symposium (ASCO-GU).** In February, cabozantinib was the subject of 14 presentations at the 2018 ASCO-GU Symposium in San Francisco. Updated results from the ongoing phase 1 trial of cabozantinib in combination with nivolumab, with or without ipilimumab, in patients with refractory genitourinary tumors were the subject of a poster presentation, with the two combination regimens demonstrating an acceptable tolerability profile, and high rates of durable responses in the previously treated metastatic UC and metastatic RCC cohorts. This phase 1 trial informed the design of CheckMate 9ER.

**Cabozantinib Data at the 2018 Multidisciplinary Head and Neck Cancers Symposium.** Also in February, cabozantinib was the subject of an oral presentation at this medical meeting held in Scottsdale, Arizona. Investigators presented results from the ongoing investigator-sponsored phase 2 trial of cabozantinib in patients with radioiodine-refractory differentiated thyroid carcinoma (DTC) in the first-line setting. Based on these results and data from other studies of cabozantinib in previously treated DTC, Exelixis plans to initiate a pivotal phase 3 study with cabozantinib in patients with advanced DTC later this year.

**Submission of Supplemental New Drug Application (sNDA) for CABOMETYX as a Treatment for Patients with Previously Treated Advanced Hepatocellular Carcinoma (HCC).** In March, Exelixis announced it had completed the submission of its sNDA to the FDA for CABOMETYX as a treatment for patients with previously treated advanced HCC. The sNDA submission is based on results from the CELESTIAL randomized pivotal phase 3 trial, data from which were presented in January at the American Society of Clinical Oncology 2018 Gastrointestinal Cancers Symposium (ASCO-GI). At ASCO-GI, Exelixis and Ipsen hosted a live briefing event for the financial community to discuss cabozantinib data presented at the conference. The replay of the briefing is available on the News & Events / Event Calendar page at [www.exelixis.com](http://www.exelixis.com).

**European Medicines Agency (EMA) Validation of the Application for a New Indication for CABOMETYX for Previously Treated Advanced HCC.** Also in March, Exelixis' partner Ipsen announced its application for variation to the CABOMETYX marketing authorization had been validated by the EMA for the addition of a new indication for patients with previously treated advanced HCC. Upon the acceptance of this filing, Exelixis will receive a \$10.0 million milestone payment per the terms of the company's collaboration agreement with Ipsen.

**CABOMETYX Receives Positive CHMP Opinion for Previously Untreated Intermediate- or Poor-Risk Advanced RCC.** In March, Exelixis' partner Ipsen received a positive opinion from the CHMP, the scientific committee of the EMA, for CABOMETYX for the first-line treatment of adults with intermediate- or poor-risk advanced RCC. The positive CHMP opinion is being reviewed by the EC, which has the authority to approve medicines for the European Union.

## Cobimetinib Highlights

**Phase 1b Results for the Combination of Cobimetinib and Atezolizumab in Metastatic Colorectal Cancer (CRC) at ASCO-GI.** In January, updated safety and efficacy results from the phase 1b clinical trial sponsored by Genentech, Inc. (a member of the Roche Group) (Genentech) evaluating cobimetinib in combination with atezolizumab in patients with metastatic CRC were presented at ASCO-GI. Initial results reported from this study presented at the 2016 ASCO Annual Meeting led to the initiation of IMblaze370 (formerly COTEZO), a phase 3 pivotal trial evaluating both the combination of cobimetinib and atezolizumab and atezolizumab alone versus regorafenib in patients with unresectable locally advanced or metastatic CRC, for which Genentech has guided it expects top-line results in the first half of 2018.

**IMspire150 TRILOGY Trial Reaches Full Enrollment.** The Roche Group recently confirmed that IMspire150 TRILOGY, its phase 3 pivotal trial evaluating the combination of cobimetinib, atezolizumab and vemurafenib in patients with first-line BRAF V600 mutation-positive metastatic or unresectable locally advanced melanoma, completed enrollment. The trial began enrolling patients in January 2017.

## Corporate Highlights

**Exclusive Licensing Agreement with StemSynergy for the Discovery and Development of Novel Anticancer Therapies.** In January, Exelixis announced it had entered into an exclusive collaboration and license agreement with StemSynergy for the discovery and development of novel oncology compounds targeting Casein Kinase 1 alpha, a component of the Wnt signaling pathway implicated in key oncogenic processes.

**Daiichi Sankyo's Submission of Regulatory Filing for Esaxerenone (CS-3150) in Japan.** In February, Exelixis announced its partner Daiichi Sankyo submitted its regulatory application for esaxerenone as a treatment for patients with hypertension to the Japanese Pharmaceutical and Medical Devices Agency. The application was based on the results of phase 3 studies including ESAX-HTN, a randomized, double-blind, three-arm parallel group comparison study evaluating the efficacy and safety of esaxerenone versus eplerenone in patients with essential hypertension in Japan. As a result of the submission, Exelixis received a \$20.0 million milestone payment in March 2018 per the collaboration agreement.

**Election of Dr. Maria Freire to Exelixis' Board of Directors.** In April, Exelixis announced the election of biomedical research executive Maria C. Freire, Ph.D. to the company's Board of Directors. Dr. Freire currently serves as President and Executive Director and as a member of the board of directors of the Foundation for the National Institutes of Health, an independent 501(c)(3) charitable organization established by Congress to support the National Institutes of Health by raising private funds for biomedical research and fostering partnerships and alliances around the world.

#### **Basis of Presentation**

Exelixis has 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 March 30, 2018, December 29, 2017 and March 31, 2017 are indicated as being as of and for the periods ended March 31, 2018, December 31, 2017 and March 31, 2017, respectively.

#### **Conference Call and Webcast**

Exelixis management will discuss the company's financial results for the first quarter of 2018 and provide a general business update during a conference call beginning at 5:00 p.m. ET / 2:00 p.m. PT today, Wednesday, May 2, 2018.

To access the webcast link, log onto [www.exelixis.com](http://www.exelixis.com) and proceed to the News & Events / Event Calendar page under the Investors & Media heading. 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 7895176 to join by phone.

A telephone replay will be available until 8:30 p.m. EDT on May 4, 2018. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 7895176. A webcast replay will also be archived on [www.exelixis.com](http://www.exelixis.com) for one year.

#### **About Exelixis**

Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model genetic systems, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. We discovered our lead compounds, cabozantinib and cobimetinib, and advanced them into clinical development before entering into partnerships with leading biopharmaceutical companies in our efforts to bring these medicines to patients globally. We are steadfast in our commitment to prudently reinvest in our business to maximize the potential of our pipeline. We intend to supplement our existing therapeutic assets with targeted business development activities and internal drug discovery - all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Exelixis recently earned a spot on Deloitte's Technology Fast 500 list, a yearly award program honoring the 500 fastest-growing companies over the past four years. For more information about Exelixis, please visit [www.exelixis.com](http://www.exelixis.com), follow @ExelixisInc on Twitter or like Exelixis, Inc. on Facebook.

#### **Forward-Looking Statements**

This press release contains forward-looking statements, including, without limitation, statements related to: the potential for cabozantinib to become an oncology franchise with global impact and Exelixis' commitment to maximizing its opportunity to help patients across multiple tumor types; Exelixis' plans to conduct future clinical studies; Exelixis' expectations related to the receipt of milestone payments in connection with the EC's approval of cabozantinib as a first-line treatment of advanced RCC and the EMA's validation of Ipsen's application for variation to the CABOMETYX marketing authorization for the added indication of patients with previously treated advanced HCC; Exelixis' guidance for 2018 total costs and operating expenses, including non-cash costs and expenses; Exelixis' plans to initiate a pivotal phase 3 study with cabozantinib in patients with advanced DTC later this year; Exelixis' expectation of top-line results in the first half of 2018 from the phase 3 pivotal trial of cobimetinib in combination with Genentech's atezolizumab in advanced CRC; Exelixis' plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery; and Exelixis' mission to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Words such as "focused," "mission," "future," "expect," "plans," "committed," "will," "guidance," "commitment," "potential," "intend," 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, COMETRIQ and COTELLIC and the availability of sufficient coverage and adequate reimbursement for these products; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; 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 availability of data at the referenced times; Exelixis' dependence on its relationship with its collaboration partners, including the level of their investment in the resources necessary to successfully commercialize partnered compounds in the territories where they are approved; 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; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its product; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; 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 SEC on February 26, 2018, 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 2, 2018. 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.

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## EXELIXIS, INC.

### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Revenues:		
Net product revenues	\$ 134,272	\$ 68,877
Collaboration revenues	78,074	12,010
Total revenues	212,346	80,887
Operating expenses:		
Cost of goods sold	5,639	3,203
Research and development	37,757	23,210
Selling, general and administrative	52,643	34,288
Total operating expenses	96,039	60,701
Income from operations	116,307	20,186
Other income (expense), net:		
Interest income	1,895	1,113
Interest expense	—	(4,420 )
Other, net	169	(45 )
Total other income (expense), net	2,064	(3,352 )
Income before income taxes	118,371	16,834
Provision for income taxes	2,514	134
Net income	\$ 115,857	\$ 16,700
Net income per share, basic	\$ 0.39	\$ 0.06
Net income per share, diluted	\$ 0.37	\$ 0.05
Shares used in computing net income per share, basic	296,421	290,870
Shares used in computing net income per share, diluted	313,691	309,535

## EXELIXIS, INC.

### CONDENSED CONSOLIDATED BALANCE SHEET DATA

(in thousands)

(unaudited)

	<b>March 31, 2018</b>	<b>December 31, 2017 <sup>(1)</sup></b>
Cash and investments <sup>(2)</sup>	\$ 525,634	\$ 457,176
Working capital	\$ 480,821	\$ 369,704
Total assets	\$ 774,915	\$ 655,294
Total stockholders' equity	\$ 669,766	\$ 284,961

(1) Derived from the audited consolidated financial statements.

(2) Cash and investments include cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments. Short- and long-term restricted cash and investments totaled \$2.0 million as of March 31, 2018 and \$5.2 million as of December 31, 2017.

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