# Exelixis Announces First Quarter 2020 Financial Results and Provides Corporate Update

May 5, 2020

***- Total Revenue of $226.9 Million, Cabozantinib Franchise Revenue of $193.9 Million -***

***- GAAP Diluted EPS of $0.15, Non-GAAP Diluted EPS of $0.19 -***

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

ALAMEDA, Calif.--(BUSINESS WIRE)--May 5, 2020-- Exelixis, Inc. (Nasdaq: EXEL) today reported financial results for the first quarter of 2020 and provided an update on progress toward fulfilling its key corporate objectives, as well as commercial and clinical development milestones.

“Exelixis remained productive with strong performance in the first quarter of 2020, despite the significant challenges introduced by the COVID-19 pandemic in the U.S. and around the world,” said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. “I’m proud of the commitment demonstrated by our team to help patients with cancer fight their disease in these difficult times, while ensuring the safety of our employees and oncology healthcare professionals. Patient access to our medicines remains a top priority for Exelixis, both on the commercial and investigational fronts.”

“Recently, we and our partner Bristol Myers Squibb announced positive top-line results from CheckMate -9ER, the pivotal phase 3 study evaluating the combination of nivolumab and cabozantinib in first-line RCC,” continued Dr. Morrissey. “The trial met its primary endpoint of progression-free survival, as well as secondary endpoints of overall survival and objective response rate. Together with Bristol Myers Squibb, we are now moving rapidly to submit regulatory applications in the U.S. and European Union in the next few months. We look forward to continuing to provide updates on our other programs and milestones as the year progresses.”

**First Quarter 2020 Financial Results**

**Total revenues** for the quarter ended March 31, 2020 were $226.9 million, compared to $215.5 million for the comparable period in 2019.

Total revenues for the quarter ended March 31, 2020 included net product revenues of $193.9 million, compared to $179.6 million for the comparable period in 2019. The increase in net product revenues reflected an increase in the average net selling price and an increase in sales volume.

Collaboration revenues, comprising license revenues and collaboration services revenues, were $33.0 million for the quarter ended March 31, 2020, compared to $35.9 million for the comparable period in 2019. The decrease in collaboration revenues was primarily related to a decrease in the recognition of milestone related revenues, which was partially offset by higher royalty revenues for the sales of cabozantinib outside of the U.S. generated by Exelixis’ partner, Ipsen Pharma SAS (Ipsen).

**Research and development expenses** for the quarter ended March 31, 2020 were $101.9 million, compared to $63.3 million for the comparable period in 2019. The increase in research and development expenses was primarily related to the increases in clinical trial costs and personnel expenses. The increase in clinical trial costs was primarily due to costs associated with the expanding clinical trial program for cabozantinib, which includes COSMIC-312, COSMIC-313 and COSMIC-021. The increase in personnel expenses was primarily due to an increase in headcount to support Exelixis’ expanding discovery and development efforts.

**Selling, general and administrative expenses** for the quarter ended March 31, 2020 were $62.9 million, compared to $60.1 million for the comparable period in 2019. The increase in selling, general and administrative expenses was primarily related to increases in the Branded Prescription Drug Fee and personnel expenses, which were partially offset by decreases in marketing costs and corporate giving. The increase in personnel expenses was primarily due to an increase in administrative headcount to support Exelixis’ commercial and research and development organizations.

**Provision for income taxes** for the quarter ended March 31, 2020 decreased to $11.4 million, compared to $14.9 million for the comparable period in 2019, primarily due to a decrease in pre-tax income.

**GAAP net income** for the quarter ended March 31, 2020 was $48.6 million, or $0.16 per share, basic and $0.15 per share, diluted, compared to GAAP net income of $75.8 million, or $0.25 per share, basic and $0.24 per share, diluted, for the comparable period in 2019. The decrease in GAAP net income was primarily related to an increase in research and development expenses, which was partially offset by an increase in net product revenues.

**Non-GAAP net income** for the quarter ended March 31, 2020 was $59.4 million, or $0.19 per share, basic and $0.19 per share, diluted, compared to non-GAAP net income of $85.5 million, or $0.28 per share, basic and $0.27 per share, diluted, for the comparable period in 2019. Non-GAAP net income excludes stock-based compensation, adjusted for the related income tax effect.

**Cash and investments** increased $51.8 million during the quarter ended March 31, 2020 to over $1.4 billion.

**Non-GAAP Financial Measures**

To supplement Exelixis’ financial results presented in accordance with U.S. Generally Accepted Accounting Principles (GAAP), Exelixis presents non-GAAP net income (and the related per share measures), which excludes from GAAP net income (and the related per share measures) stock-based compensation expense, adjusted for the related income tax effect for all periods presented.

Exelixis believes that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, Exelixis believes that these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Exelixis' results from period to period, and to identify operating trends in Exelixis' business. Exelixis has excluded stock-based compensation expense, adjusted for the related income tax effect, because it is a non-cash item that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented. Exelixis also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate its business and to make operating decisions.

These non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Exelixis encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations, to more fully understand Exelixis' business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

**2020 Financial Guidance**

Exelixis is maintaining the following previously provided financial guidance for fiscal year 2020:

| | |
|---|---|
| Total revenues | $850 million - $900 million |
| Net product revenues | $725 million - $775 million |
| Cost of goods sold | 4% - 5% of net product revenues |
| Research and development expenses(1) | $460 million - $500 million |
| Selling, general and administrative expenses(2) | $230 million - $250 million |
| Effective tax rate | 20% - 22% |
| Cash and investments(3) | $1.5 billion - $1.6 billion |

(1) Includes $25 million of non-cash stock-based compensation expense.
(2) Includes $30 million of non-cash stock-based compensation expense.
(3) This cash guidance does not include any potential new business development activity, which remains a key priority for Exelixis as it continues to build toward becoming a multi-product oncology company.

**Cabozantinib Highlights**

**Continued Growth in Cabozantinib Franchise Net Product Revenues and Royalties.** Net product revenues generated by the cabozantinib franchise in the U.S. were $193.9 million during the first quarter of 2020, an increase of 8.0% year-over-year, with net product revenues of $189.2 million from CABOMETYX and $4.7 million from COMETRIQ® (cabozantinib). Based upon cabozantinib-related revenues generated by Exelixis' partner Ipsen in the first quarter of 2020, Exelixis earned $17.9 million in royalty revenues.

**Further Expansion of Prostate Cancer Cohort in Phase 1b COSMIC-021 Trial of Cabozantinib in Combination with Atezolizumab in Patients with Advanced Solid Tumors.** In January 2020, Exelixis announced plans to further expand an existing metastatic castration-resistant prostate cancer (mCRPC) cohort (Cohort 6) of COSMIC-021, the phase 1b trial of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. Cohort 6, which was previously expanded from 30 to 80 patients in July 2019, will now include up to 130 patients.

**Presentation of Clinical Results from CheckMate 040 Clinical Trial of the Combination of Cabozantinib and Nivolumab with or without Ipilimumab in Advanced Hepatocellular Carcinoma (HCC).** In January 2020, Exelixis announced phase 1/2 clinical trial results from the combination of cabozantinib and nivolumab with or without ipilimumab in advanced HCC. Data from the cabozantinib combination cohort of the CheckMate 040 trial were presented on Friday, January 24th at American Society of Clinical Oncology's (ASCO) Gastrointestinal Cancers Symposium, which was held in San Francisco, California. These data support Exelixis' clinical development program of cabozantinib plus immune checkpoint inhibitors in advanced HCC, including the ongoing COSMIC-312 phase 3 pivotal trial of cabozantinib plus atezolizumab versus sorafenib in previously untreated patients.

**Readout of Phase 1b COSMIC-021 Trial mCRPC Cohort at ASCO's Genitourinary Cancers Symposium.** In February 2020, Exelixis announced positive efficacy and safety results from an interim analysis of the mCRPC Cohort 6 of COSMIC-021. The data were presented on Thursday, February 13th at ASCO's Genitourinary Cancers Symposium, which was held in San Francisco, California. Based on regulatory feedback from the U.S. Food and Drug Administration (FDA) and if supported by the clinical data from the recently expanded existing cohort and added mCRPC cohorts from COSMIC-021, Exelixis intends to file with the FDA for accelerated approval in an mCRPC indication as early as 2021.

**Enrollment Completion of First 100 Patients in Phase 3 COSMIC-311 Pivotal Trial of Cabozantinib in Relapsed Radioiodine (RAI)-Refractory Differentiated Thyroid Cancer (DTC).** In February 2020, Exelixis announced enrollment of the first 100 patients in COSMIC-311, a phase 3 pivotal trial evaluating CABOMETYX versus placebo in patients with RAI-refractory DTC who have progressed after up to two vascular endothelial growth factor receptor-targeted therapies.

**Exelixis Partner Takeda Pharmaceutical Company Limited (Takeda) Receives Approval in Japan for CABOMETYX Tablets for the Treatment of Curatively Unresectable or Metastatic Renal Cell Carcinoma (RCC).** In March 2020, Exelixis announced that Takeda, its partner responsible for the clinical development and commercialization of CABOMETYX in Japan, received approval from the Japanese Ministry of Health, Labour and Welfare to manufacture and market CABOMETYX as a treatment for patients with curatively unresectable or metastatic RCC. Cabozantinib continues to expand its global footprint, where it is currently approved in 55 countries.

**Positive Top-line Results from Pivotal Phase 3 CheckMate -9ER Trial Evaluating Nivolumab in Combination with Cabozantinib in Previously Untreated Advanced RCC.** In April 2020, Exelixis and Bristol Myers Squibb (BMS) announced that CheckMate -9ER, the pivotal phase 3 trial evaluating nivolumab in combination with cabozantinib compared to sunitinib in previously untreated advanced or metastatic RCC, met its primary endpoint of progression-free survival at final analysis, as well as the secondary endpoints of overall survival at a pre-specified interim analysis, and

objective response rate. This preliminary analysis of data showed a favorable safety profile for the combination of a 40 mg dose of cabozantinib with nivolumab, with a low frequency of treatment discontinuations due to adverse events. Detailed results will be submitted for presentation at an upcoming medical conference.

**Cabozantinib Data Presentations at the 2020 ASCO Annual Meeting.** Cabozantinib will be the subject of 12 presentations at this year's meeting, which has adopted a virtual format as a result of the COVID-19 pandemic. Data presentations will include results from non-small cell lung cancer (NSCLC), mCRPC and urothelial carcinoma cohorts of COSMIC-021, as well as updates from other externally sponsored studies.

**Corporate Updates**

**COVID-19 Update.** To date, the COVID-19 pandemic has had a relatively modest impact on Exelixis' business operations, in particular on Exelixis' clinical trial and drug discovery activities, and the company is undertaking considerable efforts to mitigate the various problems presented by this crisis. For further details and descriptions of the COVID-19 pandemic's actual impact, Exelixis' mitigation efforts and the risks facing Exelixis if the COVID-19 pandemic continues and grows in severity, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations—COVID-19 Update" in Part I, Item 2 and "Risk Factors" in Part II, Item 1A of Exelixis' Quarterly Report on Form 10-Q expected to be filed with the Securities and Exchange Commission on May 5, 2020.

**Exelixis Outlines Key Priorities and Anticipated Milestones for 2020-21.** In January 2020, Exelixis announced its key priorities and anticipated milestones for 2020-21, including generating top-line data from ongoing trials with label-enabling potential, initiating new pivotal trials, and progressing its mid-stage and early pipeline, with up to three new investigational new drug filings in 2020. Subject to the challenges and risks of the Exelixis business, including a modest actual and potential additional impact from the ongoing COVID-19 pandemic, Exelixis is maintaining its guidance for clinical trial enrollment and top-line data timelines for COSMIC-311, COSMIC-312, COSMIC-313, COSMIC-021, EXAMINER and XL092, as well as for the initiation of three phase 3 pivotal trials evaluating cabozantinib in combination with atezolizumab in advanced NSCLC, mCRPC and RCC. Exelixis intends to make appropriate investments to maximize the clinical development opportunities for CABOMETYX, while concurrently working to advance a pipeline of potential new Exelixis medicines through internal drug discovery and business development.

**George A. Scangos, Ph.D. Retires from Exelixis Board of Directors.** In March 2020, Exelixis announced that George A. Scangos, Ph.D. notified the company of his decision to retire from the Exelixis Board of Directors. Dr. Scangos will not stand for re-election to the Board of Directors at the company's 2020 Annual Meeting of Stockholders on May 20, 2020; his resignation from the Board will take effect that same day. Dr. Scangos cited his multiple professional and philanthropic commitments as principal reasons for his decision to retire from the Exelixis Board of Directors.

**Exelixis Receives Notice of Additional Paragraph IV Certifications.** Today, May 5, 2020, Exelixis received notice from MSN Pharmaceuticals, Inc. that it had amended its Abbreviated New Drug Application (ANDA), originally filed with the FDA in September 2019, to add two previously-unasserted CABOMETYX Orange Book-listed patents: U.S. Patent No. 7,579,473, the composition of matter patent, and U.S. Patent No. 8,497,284, a method of use patent. Exelixis is well prepared to respond and will vigorously defend its cabozantinib intellectual property estate.

**Basis of Presentation**

Exelixis has 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 April 3, 2020, January 3, 2020 and March 29, 2019 are indicated as being as of and for the periods ended March 31, 2020, December 31, 2019 and March 31, 2019, respectively.

**Conference Call and Webcast**

Exelixis management will discuss the company's financial results for the first quarter of 2020 and provide a general business update during a conference call beginning at 5:00 p.m. EDT / 2:00 p.m. PDT today, Tuesday, May 5, 2020.

To access the webcast link, log onto 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 8465574 to join by phone.

A telephone replay will be available until 8:00 p.m. EDT on May 7, 2020. Access numbers for the telephone replay are: 855-859-2056 (domestic) and 404-537-3406 (international); the passcode is 8465574. A webcast replay will also be archived on 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 system genetics, 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. Our discovery efforts have resulted in four approved products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing 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 is a member of Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. For more information about Exelixis, please visit 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: Exelixis' plans with BMS to submit regulatory applications for the combination of nivolumab and cabozantinib as a treatment for first-line RCC; Exelixis' 2020 financial guidance; Exelixis' plans to further expand Cohort 6 of COSMIC-021; Exelixis' intention to file with the FDA for accelerated approval of the combination of cabozantinib and atezolizumab in an mCRPC indication, if supported by the clinical data; Exelixis' and BMS' plans to submit detailed results from the CheckMate -9ER trial for presentation at an upcoming medical conference; Exelixis' plans to present data from NSCLC, mCRPC and urothelial carcinoma cohorts

of COSMIC-021 at the 2020 ASCO Annual Meeting, as well as updates from other externally sponsored studies; Exelixis' key priorities and anticipated milestones for 2020-21; Exelixis' guidance for clinical trial initiation, enrollment and top-line data; and 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. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and 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 continuing COVID-19 pandemic and its impact on Exelixis' research and development operations, including Exelixis' ability to initiate new clinical trials and clinical trial sites, enroll clinical trial patients, conduct trials per protocol, and conduct drug research and discovery operations and related activities; the degree of market acceptance of CABOMETYX and other Exelixis products in the indications for which they are approved and in the territories where they are approved, and Exelixis' and its partners' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX and other Exelixis products in comparison to competing products; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' ability to maintain and scale adequate sales, marketing, market access and product distribution capabilities for its products or to enter into and maintain agreements with third parties to do so; the availability of data at the referenced times; the potential failure of cabozantinib and other Exelixis product candidates, both alone and in combination with other therapies, to demonstrate safety and/or efficacy in clinical testing; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications, their adherence to their obligations under relevant collaboration agreements and the level of their investment in the resources necessary to complete clinical trials or successfully commercialize partnered compounds in the territories where they are approved; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating cabozantinib, cobimetinib or esaxerenone; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products; 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 Securities and Exchange Commission (SEC) on February 25, 2020, 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 5, 2020. All forward-looking statements in this press release are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein, except as required by law.



**EXELIXIS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF INCOME**
(in thousands, except per share amounts)
(unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Revenues: | | |
| Net product revenues | $ 193,880 | $ 179,581 |
| License revenues | 20,879 | 25,564 |
| Collaboration services revenues | 12,156 | 10,342 |
| Total revenues | 226,915 | 215,487 |
| Operating expenses: | | |
| Cost of goods sold | 9,289 | 7,501 |
| Research and development | 101,877 | 63,289 |
| Selling, general and administrative | 62,940 | 60,138 |
| Total operating expenses | 174,106 | 130,928 |
| Income from operations | 52,809 | 84,559 |
| Interest income | 7,220 | 6,087 |
| Other income, net | 6 | 25 |
| Income before income taxes | 60,035 | 90,671 |
| Provision for income taxes | 11,423 | 14,896 |
| Net income | $ 48,612 | $ 75,775 |
| Net income per share: | | |
| Basic | $ 0.16 | $ 0.25 |
| Diluted | $ 0.15 | $ 0.24 |
| Weighted-average common shares outstanding: | | |
| Basic | 305,388 | 300,542 |
| Diluted | 315,839 | 314,644 |

**EXELIXIS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEET DATA**
(in thousands)
(unaudited)

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Cash and investments | $ 1,440,404 | $ 1,388,628 |
| Working capital | $ 996,419 | $ 868,444 |
| Total assets | $ 1,955,604 | $ 1,885,670 |
| Total stockholders' equity | $ 1,747,652 | $ 1,685,970 |

**EXELIXIS, INC.**
**RECONCILIATION OF GAAP NET INCOME TO NON-GAAP NET INCOME**
(in thousands, except per share amounts)
(unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| GAAP net income | $ 48,612 | $ 75,775 |
| Adjustments: | | |
| Stock-based compensation - research and development expenses [1] | 5,086 | 4,306 |
| Stock-based compensation - selling, general and administrative expenses [1] | 8,896 | 8,223 |
| Income tax effect of the above adjustments | (3,180) | (2,809) |
| Non-GAAP net income | $ 59,414 | $ 85,495 |
| GAAP net income per share: | | |
| Basic | $ 0.16 | $ 0.25 |
| Diluted | $ 0.15 | $ 0.24 |
| Non-GAAP net income per share: | | |
| Basic | $ 0.19 | $ 0.28 |
| Diluted | $ 0.19 | $ 0.27 |
| Weighted-average common shares outstanding: | | |
| Basic | 305,388 | 300,542 |
| Diluted | 315,839 | 314,644 |

(1) Non-cash stock-based compensation expense used for GAAP reporting in accordance with Accounting Standards Codification Topic 718, *Compensation—Stock Compensation*

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