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Testo del comunicato

Vedi allegato.

CTI BIOPHARMA REPORTS FIRST QUARTER 2016 FINANCIAL RESULTS

SEATTLE, WA, May 10, 2016 - CTI BioPharma Corp. (NASDAQ and MTA:CTIC) today reported financial results for the first quarter ended March 31, 2016.

"We continue to believe in the potential of pacritnib to help patients in need and are working to address the clinical hold on the pacritinib program," said James A. Bianco, M.D., President and Chief Executive Officer of CTI BioPharma. "While we work with the FDA to seek to address their recommendations for getting pacritinib off hold, we have made progress in our efforts to support patients who were deriving benefit from pacritinib at the time of the clinical hold by providing pacritinib under a single patient IND program and, separately, to individual patients for "compassionate use" under the FDA's emergency Expanded Access program. We are pleased that certain investigator-sponsored trials can resume as the agency has removed the clinical hold at their sites."

"We are also preparing for the release of top-line results from the PERSIST-2 Phase 3 clinical trial, which we expect to report in the third quarter of 2016," added Dr. Bianco.

First Quarter and Recent Events

- In the first quarter, patient enrollment was completed in the PERSIST-2 Phase 3 clinical trial of pacritinib for the treatment of patients with intermediate and high-risk myelofibrosis. PERSIST-2 is evaluating pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter (≤100,000/μL). In February, the U.S. Food and Drug Administration (FDA) placed a full clinical hold on pacritinib clinical studies, and as such, all patients participating in the PERSIST-2 clinical trial discontinued pacritinib treatment. Although not all patients enrolled were able to reach the primary endpoint evaluation at 24 weeks from randomization prior to the full clinical hold on pacritinib, approximately two thirds of the enrolled patients reached or exceeded the 24-week endpoint evaluation. The Company believes there is sufficient power to reach statistical significance of the primary objectives. Top-line results from the PERSIST-2 Phase 3 trial of pacritinib are expected in the third quarter of 2016.

- In March 2016, the FDA expressed interest in allowing patients who were receiving benefit from pacritinib treatment at the time the clinical hold was imposed to submit requests to the FDA to resume pacritinib treatment under a Single Patient IND (SPI) program on a case-by-case basis. The Company has been working with investigators in submitting SPI requests to the FDA. Separately, the FDA has informed clinical investigators that emergency requests may be submitted to the FDA for individual patient Expanded Access to pacritinib.

Expanded Access, sometimes called "compassionate use," is the use outside of a clinical trial of an investigational medical product. The Company recently learned that the FDA has released the clinical hold on certain investigator-sponsored trials that were evaluating pacritinib.

- In April 2016, researchers presented findings from an investigator-sponsored preclinical study indicating that pacritinib, an inhibitor of JAK2, FLT3, IRAK1 and CSF1R may potentially be effective in reducing survival of myelofibrosis and acute myeloid leukemia (AML) repopulating cells. Further, this study also demonstrated that the combination of pacritinib at low nanomolar concentrations with dasatinib may eliminate self-renewing leukemia stem cells in blast crisis of chronic myeloid leukemia (CML) with minimal toxicity toward normal progenitors. These and other findings were presented at the American Association of Cancer Research (AACR) Annual Meeting.

First Quarter Financial Results

Total revenues for the first quarter ended March 31, 2016, were $36.5 million compared to $2.7 million for the same period in 2015. The increase in total revenue for the first quarter of 2016 is primarily due to recognition of $32 million in milestone payments related to pacritinib. The Company had previously received a cash advance for these milestone payments in the second quarter of 2015 that was accounted for as long-term debt until the achievement of the associated milestones in the first quarter of 2016. Additionally, net product revenues of PIXUVRI for the first quarter ended March 31, 2016 increased to $1.2 million compared to $0.8 million for the same period in 2015.

GAAP operating income for the first quarter ended March 31, 2016, was $4.1 million compared to GAAP operating loss of $27.5 million for the same period in 2015. Non-GAAP operating income, which excludes non-cash share-based compensation expense, for the first quarter ended March 31, 2016, was $8.0 million compared to the non-GAAP operating loss of $23.1 million for the same period in 2015. The Company’s operating income for the first quarter ended March 31, 2016, as compared an operating loss for the same period in 2015, is primarily due to recognition of $32 million in milestone payments related to pacritinib as mentioned above. Non-cash share-based compensation expense for the first quarter ended March 31, 2016, was $3.8 million compared to $4.3 million for the same period in 2015. For information on CTI BioPharma’s use of this non-GAAP measure and a reconciliation of such measure to GAAP operating loss, see the section below entitled “Non-GAAP Financial Measures.”

Net income for the first quarter of 2016 was $3.3 million, or $0.01 per share, compared to a net loss of $28.6 million, or ($0.16) per share, for the same period in 2015.

As of March 31, 2016, cash and cash equivalents totaled $104.6 million, compared to $128.2 million as of December 31, 2015.

Information required by CONSOB pursuant to section 114, paragraph 5, of the Italian Legislative Decree no. 58/98

Report on possible failure to comply with covenants

To the knowledge of CTI BioPharma's management, CTI BioPharma and its subsidiaries are in compliance with all covenants, negative pledges and other provisions concerning long-term debt.

Business and financial plan

CTI BioPharma's strategy is to become a leader in the acquisition, development and commercialization of novel therapeutics for the treatment of blood-related cancers. The key elements of CTI BioPharma's strategy to achieve this goal are to:

- **Commercialize PIXUVRI.** Together with Servier, CTI BioPharma intends to continue its efforts to commercialize PIXUVRI in Europe. CTI BioPharma is currently focused on educating physicians on the unmet medical need for PIXUVRI among physicians in the countries where PIXUVRI is available. A successful outcome from the post-authorization trial, PIX306, would enable the Company to potentially obtain full marketing authorization from the European Commission and expand the market potential for PIXUVRI.

- **Develop Pacritinib in Myelofibrosis.** CTI BioPharma intends to develop and commercialize pacritinib for adult patients with myelofibrosis.

- **Continue to Develop Other Pipeline Programs.** CTI BioPharma believes that it is important to maintain a diverse pipeline to sustain its future growth. To accomplish this, CTI BioPharma intends to continue advancing the development of its other pipeline candidates through cooperative group and investigator sponsored trials. CTI BioPharma believes that sponsoring such trials provides a more economical approach for further developing investigational products.

- **Evaluate Strategic Product Collaborations to Accelerate Development and Commercialization.** Where CTI BioPharma believes it may be beneficial, it will evaluate additional potential collaborations to broaden and accelerate clinical trial development and potential commercialization of product candidates. Collaborations have the potential to generate non-equity based operating capital, supplement internal expertise and provide access to the marketing, sales and distribution capabilities of its collaborators in specific territories.

- **Identify and Acquire Additional Pipeline Opportunities.** CTI BioPharma's current pipeline is the result of licensing and acquiring assets that it believes were initially undervalued opportunities. CTI BioPharma plans to continue to seek out additional product candidates in an opportunistic manner.

About CTI BioPharma Corp.

CTI BioPharma Corp. (NASDAQ and MTA: CTIC) is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and healthcare providers. CTI BioPharma has a commercial presence in Europe with respect to PIXUVRI® and a late-stage development pipeline, including pacritinib for the treatment of patients with myelofibrosis. CTI BioPharma is headquartered in Seattle, Washington, with offices in London and Milan under the name CTI Life Sciences Limited. For additional information and to sign up for email alerts and get RSS feeds, please visit www.ctibiopharma.com.

Non-GAAP Financial Measures

CTI BioPharma has provided in this press release the historical financial measure of income in 2016 from operations, excluding non-cash share-based compensation expense, which is a non-GAAP measure, for the first quarter ended March 31, 2016 and March 31, 2015. Due to varying available valuation methodologies, subjective assumptions and the different GAAP accounting treatment of different award types that companies can use under ASC Topic 718, CTI BioPharma's management believes that providing a non-GAAP financial measure that excludes non-cash share-based compensation can enhance management's and investors' comparison of CTI BioPharma's operating results over different periods of time as compared to the operating results of other companies.

CTI BioPharma's use of a non-GAAP financial measure has limitations and should not be considered in isolation from, or as a substitute for, financial information prepared in accordance with GAAP. One limitation is that CTI BioPharma's reported non-GAAP income in 2016 from operations results in the exclusion of a recurring expense, since CTI BioPharma expects that share-based compensation will continue to be a significant recurring expense in CTI BioPharma's business. A second limitation is that CTI BioPharma's methodology for calculating non-GAAP loss from operations, which only excludes the component of share-based compensation, may differ from the methodology CTI BioPharma's peer companies utilize to the extent they report non-GAAP income in 2016 from operations or similarly titled measures. Accordingly, CTI BioPharma's non-GAAP income in 2016 from operations may not necessarily be comparable to similarly titled measures of other companies. Investors are urged to review the reconciliation of these non-GAAP measures to their most directly comparable GAAP financial measures. A reconciliation of CTI BioPharma's non-GAAP financial measures to their most directly comparable GAAP measures has been provided in the financial statement tables included below in this press release.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements are subject to a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of CTI BioPharma's securities. Such statements include, but are not limited to, statements regarding CTI BioPharma's expectations with respect to the potential of pacritinib, the development of CTI BioPharma and its product and product candidate portfolio, including the advancement of pacritinib, CTI BioPharma's ability to achieve its goals in 2016 and beyond and the timing of the release of PERSIST-2 Phase 3 clinical trial top-line results, the ability to provide pacritinib to patients under a Single Patient IND program or expanded access program, CTI BioPharma's intent to continue efforts to commercialize PIXUVRI in Europe and its ability to obtain full marketing authorization from the European Commission and expand the market potential for PIXUVRI, CTI BioPharma's plans to continue advancing the development of its pipeline candidates through cooperative group and investigator-sponsored trials. The statements are based on assumptions about many important factors and information currently available to us to the extent we have thus far had an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. Risks that contribute to the uncertain nature of the forward-looking statements include, among others, risks associated with the biopharmaceutical industry in general and with CTI BioPharma and its product and product candidate portfolio in particular including, among others, risks associated with the following: the clinical hold on pacritinib may not be removed in full or in part on a timely basis or at all, that CTI BioPharma cannot predict or guarantee the pace or geography of enrollment of its clinical trials, that CTI BioPharma cannot predict or guarantee the outcome of preclinical and clinical studies, the potential failure of pacritinib to prove safe and effective as determined by the FDA and/or the European Medicines Agency, changes to study protocol or design or sample size to address any patient safety, efficacy or other issues raised by the FDA or otherwise, that the FDA may expand its information request or fail to release the clinical hold or take other actions, that top-line results observed to date may differ from future results or that different conclusions or considerations may qualify such results once existing data has been more fully evaluated, clinical trial results, that CTI BioPharma may not obtain favorable determinations by other regulatory, patent and administrative governmental authorities, that CTI BioPharma may experience delays in the commencement of preclinical and clinical studies, risks related to the costs of developing pacritinib and CTI BioPharma's other product candidates, and other risks, including, without limitation, competitive factors, technological developments, that CTI BioPharma may not be able to sustain its current cost controls or further reduce its operating expenses, that CTI BioPharma may not achieve previously announced goals, contractual milestones and objectives as or when projected, that CTI BioPharma's average net operating burn rate may increase, that CTI BioPharma will continue to need to raise capital to fund its operating expenses, but may not be able to raise sufficient amounts to fund its continued operation as well as other risks listed or described from time to time in

CTI BioPharma's most recent filings with the SEC on Forms 10-K, 10-Q and 8-K. Except as required by law, CTI BioPharma does not intend to update any of the statements in this press release upon further developments.

PIXUVRI is a registered trademark of CTI BioPharma Corp.

Source: CTI BioPharma Corp.

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CTI BioPharma Corp.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Product sales, net	$ 1,223	$ 805
License and contract revenue	35,252	1,923
Total revenues	36,475	2,728
Operating costs and expenses:		
Cost of product sold	190	190
Research and development	20,846	17,471
Selling, general and administrative	11,312	12,297
Other operating expense	—	253
Total operating costs and expenses	32,348	30,211
Income (loss) from operations	4,127	(27,483)
Non-operating income (expense):		
Interest expense	(714)	(494)
Amortization of debt discount and issuance costs	(101)	(180)
Foreign exchange gain (loss)	198	(728)
Other non-operating expense	(519)	—
Net income (loss) before noncontrolling interest	2,991	(28,885)
Noncontrolling interest	321	288
Net income (loss) attributable to CTI	$ 3,312	$ (28,597)
Net income (loss) per common share:		
Basic	$ 0.01	$ (0.16)
Diluted	$ 0.01	$ (0.16)
Shares used in calculation of earnings (loss) per common share:		
Basic	277,930	173,936
Diluted	278,156	173,936

Balance Sheet Data (unaudited):	(amounts in thousands)	
	March 31, 2016	December 31, 2015
Cash and cash equivalents	$ 104,641	$ 128,182
Working capital	67,588	62,566
Total assets	123,441	144,197
Current portion of long-term debt	7,285	37,371
Long-term debt, less current portion	17,314	19,124
Total shareholders' equity	54,743	47,413

Non-GAAP Reconciliations
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
As reported - income (loss) from operations (GAAP)	$ 4,127	$ (27,483)
As reported - share-based compensation expense (GAAP)	3,826	4,336
As adjusted - income (loss) from operations (Non-GAAP)	$ 7,953	$ (23,147)

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