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Testo del comunicato

Vedi allegato.

CTI BIOPHARMA REPORTS FIRST QUARTER 2015 FINANCIAL RESULTS

- Late-breaking Abstract for Pacritinib Accepted for Presentation at ASCO -

- Conference Call Scheduled for Today at 4:30 p.m. Eastern Time -

SEATTLE, Wash., May 6, 2015–CTI BioPharma Corp. (NASDAQ and MTA: CTIC) today reported financial results for the first quarter ended March 31, 2015.

"After reporting positive top-line results from the PERSIST-1 Phase 3 clinical trial of pacritinib during the quarter, we have subsequently received positive feedback from a number of treating physicians who are excited by the potential opportunity for pacritinib to meet a current unmet medical need in the treatment of patients with myelofibrosis, specifically in the portion of patients that have low-blood platelets as a result of their disease or other treatment," said James A. Bianco, M.D., CTI BioPharma's President and CEO. "We look forward to the oral presentation of data from this trial at ASCO and remain focused on completing the second pacritinib Phase 3 trial, PERSIST-2, in the second-half of this year and, with our partner Baxter, starting a planned regulatory submission late in 2015."

First Quarter 2015 Financial Results

Total revenues for the quarter ended March 31, 2015 were $2.7 million compared to $1.4 million for the same period in 2014, which includes PIXUVRI net product revenues of $0.8 million and license contract revenues of $1.9 million for the quarter ended March 31, 2015 compared to $1.3 million and $0.1 million, respectively, for the same period in 2014.

The non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the quarter ended March 31, 2015 was $23.1 million, compared to non-GAAP operating loss of $19.8 million for the same period in 2014. The GAAP operating loss for the quarter ended March 31, 2015 was $27.5 million, compared to a GAAP operating loss of $27.7 million for the same period in 2014. Non-cash share-based compensation expense for the quarter ended March 31, 2015 was $4.3 million compared to $7.8 million for the same period in 2014. For information on CTI BioPharma's use of the aforementioned non-GAAP measure and a reconciliation of such measure to GAAP operating loss, see the section below entitled "Non-GAAP Financial Measures."

Net loss for the quarter ended March 31, 2015 was $28.6 million, or $0.16 per share, compared to a net loss of $29.0 million, or $0.20 per share, for the same period in 2014.

For the quarter ended March 31, 2015, cash and cash equivalents totaled $44.4 million.

2015 Financial Outlook

CTI BioPharma reaffirms prior financial guidance that it expects total revenues for 2015 will be approximately $50 million to $55 million, and it expects that non-GAAP operating loss for 2015 will be approximately $75 million to $85 million, which excludes non-cash share-based compensation expense. These financial projections are primarily based on factors previously outlined in the Company's fourth quarter and full year 2014 financial results press release.

Recent Clinical Highlights

Recent clinical highlights concerning pacritinib, a JAK2 and FLT3 inhibitor, are as follows:

- PERSIST-1, a randomized (2:1), open-label, multinational Phase 3 clinical trial evaluating the investigational agent pacritinib in patients with primary and secondary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, without exclusion for low platelet counts, met its primary endpoint of reducing spleen size by 35 percent or more from baseline to Week 24 as measured by MRI or CT, when compared with BAT, excluding treatment with JAK2 inhibitors. Additionally, the safety profile of pacritinib was generally consistent with previous Phase 2 studies.
- PERSIST-1 data will be highlighted in a late-breaking oral presentation and will be a part of the official press briefing session titled 'Targeted Therapy,' at the American Society of Clinical Oncology (ASCO) 2015 Meeting on May 30, 2015.
- Results from a Phase 2 study of pacritinib in patients with myelofibrosis were published in the journal *Blood*. Results from this study demonstrated that pacritinib is active in patients with myelofibrosis, resulting in spleen volume reduction, while producing substantial and prolonged improvement in disease-related symptoms without causing clinically significant myelosuppression.

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:

- **Successfully Commercialize PIXUVRI.** Together with Servier, CTI BioPharma intends to continue its efforts to build a successful PIXUVRI franchise in Europe as well as other markets. CTI BioPharma is currently focused on educating physicians on the unmet medical need and building brand awareness for PIXUVRI among physicians in the countries where PIXUVRI is available.
- **Develop Pacritinib in Myelofibrosis and Additional Indications.** Together with Baxter, CTI BioPharma intends to develop and commercialize pacritinib for adult patients with myelofibrosis. CTI BioPharma also intends to continue evaluation of pacritinib in other blood-related cancers, including AML and MDS, through ongoing and planned ISTs.
- **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 to advance the development of its other pipeline candidates through cooperative group sponsored trials and ISTs. 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 intends to evaluate additional 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.

Conference Call Information

CTI BioPharma management will host a conference call to review its first quarter 2015 financial results and provide an update on business activities. The event will be held today at 1:30 p.m. PDT / 4:30 p.m. EDT / 10:30 p.m. CET. Participants can access the call at 1-888-395-3227 (domestic) or +1 719-457-2664 (international). To access the live audio webcast or the subsequent archived recording, visit CTI BioPharma's website, www.ctibiopharma.com. Webcast and telephone replays of the conference call will be available approximately two hours after completion of the call. Callers can access the replay by dialing 1-888-203-1112 (domestic) or +1 719-457-0820 (international). The access code for the replay is 6879970. The telephone replay will be available until Wednesday, May 13, 2015.

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 and a late-stage development pipeline, including pacritinib, CTI BioPharma's lead product candidate, which is currently being studied in a Phase 3 program 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 loss from operations, excluding non-cash share-based compensation expense, which is a non-GAAP measure, for the first quarter ended March 31, 2015, and the financial projection of loss from operations, excluding non-cash share-based compensation expense, which is a non-GAAP measure, for the 2015 fiscal year. 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 loss from operations results in the exclusion of a recurring expense, since 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 loss from operations or similarly titled measures and accordingly 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 measure for the first quarter ended March 31, 2015 to its most directly comparable GAAP measure has been provided in the financial statement tables included below in this press release.

CTI BioPharma has not included a reconciliation of its projected non-GAAP loss from operations to a projected GAAP loss from operations because the calculation of the excluded share-based compensation would require information that is presently uncertain, such as the future level of additional equity awards that will be granted to meet CTI BioPharma's compensation philosophy and objectives after taking into account the economic climate at the time of grant. In addition, the calculation is largely based on the price of CTI BioPharma's stock at the time of the specific grants (as required under ASC Topic 718), which price is variable and therefore unknowable until the grant is made. Because of the contingent nature of such factors, CTI BioPharma believes that the specific adjustment for future share-based compensation cannot be forecast with accuracy.

PIXUVRI is a registered trademark of CTI BioPharma Corp.

Source: CTI BioPharma Corp.

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 development of CTI BioPharma and its product and product candidate portfolio, the potential opportunity for pacritinib to meet a current unmet medical need in the treatment of patients with myelofibrosis, specifically in the portion of patients that have low-blood platelets as a result of their disease or other treatment, the anticipated completion of enrollment in PERSIST-2 in the second half of this year, potentially starting a regulatory submission for pacritinib late in 2015, CTI BioPharma's ability to achieve its articulated 2015 business and financial plan, goals, objectives and projections, CTI BioPharma's projected revenues and non-GAAP operating loss and the expectations and assumption on which they are based. In particular, this release addresses top line results regarding the PERSIST-1 study, and should be evaluated together with secondary endpoints, safety and additional data once such data has been more fully analyzed and is made publicly available. 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: 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, 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.

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

	Three Months Ended March 31,	
	2015	2014
Revenues:		
Product sales, net	$ 805	$ 1,268
License and contract revenue	1,923	143
Total revenues	2,728	1,411
Operating costs and expenses:		
Cost of product sold	190	145
Research and development	17,471	12,179
Selling, general and administrative	12,297	16,750
Other operating expense	253	—
Total operating costs and expenses	30,211	29,074
Loss from operations	(27,483)	(27,663)
Non-operating expense:		
Interest expense	(494)	(464)
Amortization of debt discount and issuance costs	(180)	(178)
Foreign exchange loss	(728)	(5)
Other non-operating expense	—	(886)
Net loss before noncontrolling interest	(28,885)	(29,196)
Noncontrolling interest	288	194
Net loss	$ (28,597)	$ (29,002)
Basic and diluted net loss per common share	$ (0.16)	$ (0.20)
Shares used in calculation of basic and diluted net loss per common share	173,936	142,138

Balance Sheet Data (unaudited):

	(amounts in thousands)	
	March 31, 2015	December 31, 2014
Cash and cash equivalents	$ 44,395	$ 70,933
Working capital	18,084	44,165
Total assets	63,070	92,287
Current portion of long-term debt	9,294	9,014
Long-term debt, less current portion	5,943	8,363
Total shareholders' equity	14,117	38,478

Non-GAAP Reconciliations
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2015	2014
As reported - loss from operations (GAAP)	$ (27,483)	$ (27,663)
As reported - share-based compensation expense (GAAP)	4,336	7,829
As adjusted - loss from operations (Non-GAAP)	$ (23,147)	$ (19,834)

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