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Testo del comunicato

Vedi allegato.

CTI BIOPHARMA REPORTS THIRD QUARTER 2015 FINANCIAL RESULTS

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

SEATTLE, Wash., November 5, 2015–CTI BioPharma Corp. (NASDAQ and MTA: CTIC) today reported financial results for the third quarter ended September 30, 2015.

"We are focused on preparing our NDA submission for pacritinib and are on track to submit our application to the FDA this quarter," said James A. Bianco, M.D., CTI BioPharma's President and CEO. "We also remain committed to completing the second Phase 3 trial of pacritinib, PERSIST-2, which we believe could serve as a post-approval confirmatory trial in the event our NDA application is accepted and approved under accelerated approval. Additionally, we look forward to upcoming data presentations of pacritinib and tosedostat studies at the ASH Annual Meeting in December."

Third Quarter 2015 and Recent Highlights

- In September 2015, announced plans to submit a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) with partner Baxalta Inc. for pacritinib, an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R for the treatment of patients with myelofibrosis, in the fourth quarter of 2015 and to request accelerated approval for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter (<50,000/uL) for whom there are no approved drugs. Priority review of the application will be requested at the time of NDA submission.

- In September 2015, completed registered direct offering resulting in net proceeds of approximately $15.1 million and in October 2015, completed underwritten public offering resulting in net proceeds of approximately $46.5 million.

- In November 2015, announced the upcoming presentations of data highlighting pacritinib and tosedostat at the 57th American Society of Hematology Annual Meeting (ASH) to be held December 5-8, 2015, in Orlando, FL.

Third Quarter 2015 Financial Results

Total revenues for the third quarter and the nine months ended September 30, 2015 were $1.0 million and $4.8 million, respectively, compared to $39.5 million and $42.3 million for the same periods in 2014. The decrease in total revenue is primarily due to recognition of milestone payments in 2014, specifically a $20.0 million development milestone payment received from Baxalta for completion of enrollment in the PERSIST-1 Phase 3 clinical trial of pacritinib and $17.3 million from an upfront payment under the PIXUVRI® collaboration agreement with Servier. Net product revenues of PIXUVRI for the third quarter and the nine months ended September 30, 2015 were $0.7 million and $2.4 million, respectively, compared to $2.0 million and $4.4 million for the same periods in 2014. The decrease in net product sales was primarily related to the pricing and volume variances between the periods presented as well as the decline in average exchange rate of the euro for our euro-denominated sales.

The non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the third quarter and nine months ended September 30, 2015 was $26.1 million and $77.5 million, respectively, compared to non-GAAP operating income of $11.3 million and a non-GAAP operating loss of $29.8 million for the same periods in 2014. The GAAP operating loss for the third quarter and nine months ended September 30, 2015 was $32.0 million and $90.5 million, respectively, compared to a GAAP operating income of $7.5 million and operating loss of $46.9 million for the same period in 2014. The increase in operating loss for the nine-month period is predominantly associated with the Phase 3 development program for

pacritinib and the PIX306 post-authorization Phase 3 trial for PIXUVRI as well as the milestone and the upfront payments received in the 2014 periods as mentioned above. Non-cash share-based compensation expense for the third quarter and nine months ended September 30, 2015 was $5.9 million and $13.0 million, respectively, compared to $3.8 million and $17.0 million for the same periods 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 third quarter of 2015 was $32.6 million, or $(0.19) per share, compared to a net income of $4.6 million, or $0.03 per share, for the same period in 2014. Net loss for the first nine months of 2015 was $93.8 million, or $(0.54) per share, compared to a net loss of $51.8 million, or $(0.36) per share, for the same period in 2014.

As of September 30, 2015, cash and cash equivalents totaled $46.4 million, compared to $70.9 million as of December 31, 2014. Subsequent to September 30, 2015, we received approximately $46.5 million in net proceeds from an underwritten public offering in October 2015.

2015 Financial Outlook

CTI BioPharma now expects total revenues for 2015 will be approximately $30 million to $45 million, which are primarily based upon updated current expectations regarding license and contract revenues under the agreements with Baxalta and Teva and net product sales from PIXUVRI commercial operations. 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 our current expectations regarding patient enrollment, NDA submission timing and other factors previously outlined in the Company's fourth quarter and full year 2014 financial results press release.

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.

- **Develop Pacritinib in Myelofibrosis and Additional Indications.** Together with Baxalta, 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 investigator-sponsored trials.

- **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.

Conference Call Information

CTI BioPharma management will host a conference call to review its third quarter 2015 financial results and provide an update on business activities. The event will be held today at 1:30 p.m. PST / 4:30 p.m. EST / 10:30 p.m. CET. Participants can access the call at 1-800-344-6491 (domestic) or +1 785-830-7988 (international). To access the live audio webcast or the subsequent archived recording, visit 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 4854945. The telephone replay will be available until Thursday, November 12, 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 has a commercial presence in Europe and a late-stage development pipeline, including pacritinib, CTI's lead product candidate, which is currently being studied in a Phase 3 program for the treatment of patients with myelofibrosis. CTI 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 third quarter and nine months ended September 30, 2015 and 2014, 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 third quarter and nine months ended September 30, 2015 and 2014 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, including, in particular, expectations with respect to CTI BioPharma's plan to submit a NDA to the FDA for pacritinib and request priority review and CTI BioPharma's ability to obtain priority review of such application, the potential therapeutic utility of pacritinib (such as the ability to meet a current unmet medical need in the treatment of patients with myelofibrosis and the potential for pacritinib in other blood-related cancers), completion of PERSIST-2, the potential therapeutic utility of tosedostat in the treatment of patients with AML, or AML that has evolved from MDS, the anticipated completion of enrollment in PERSIST-2, CTI BioPharma's ability to achieve its articulated business and financial plan, goals, objectives and projections, and CTI BioPharma's projected revenues and non-GAAP operating loss and the expectations and assumption on which they are based. 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 regulatory agencies may determine that the number of patients enrolled in the clinical trials supporting an application is insufficient to support approval of a product candidate, that CTI BioPharma cannot predict or guarantee the outcome of preclinical and clinical studies, that clinical trial 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 PIXUVRI, pacritinib, tosedostat 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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Contacts:
Monique Greer
+1 206-272-4343
mgreer@ctibiopharma.com

Ed Bell
+1 206-272-4345

ebell@ctibiopharma.com

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

	Three Months Ended September 30,		Nine Months Ended June 30,	
	2015	2014	2015	2014
Revenues:				
Product sales, net	$ 740	$ 2,021	$ 2,394	$ 4,437
License and contract revenue	224	37,513	2,398	37,851
Total revenues	964	39,534	4,792	42,288
Operating costs and expenses:				
Cost of product sold	831	252	1,204	599
Research and development	18,404	16,528	55,195	42,725
Selling, general and administrative	13,682	12,563	38,603	43,104
Other operating expense	—	2,719	253	2,719
Total operating costs and expenses	32,917	32,062	95,255	89,147
Income (loss) from operations	(31,953)	7,472	(90,463)	(46,859)
Non-operating income (expense):				
Interest expense	(1,288)	(472)	(2,379)	(1,403)
Amortization of debt discount and issuance costs	(40)	(185)	(351)	(547)
Foreign exchange loss	(18)	(2,455)	(561)	(2,621)
Other non-operating income (expense)	203	—	(993)	(885)
Net loss before noncontrolling interest	(33,096)	4,360	(94,747)	(52,315)
Noncontrolling interest	504	243	962	517
Net income (loss)	(32,592)	4,603	(93,785)	(51,798)
Basic net income (loss) per common share	$ (0.19)	$ 0.03	$ (0.54)	$ (0.36)
Diluted net income (loss) per common share	$ (0.19)	$ 0.03	$ (0.54)	$ (0.36)
Shares used in calculation of basic earnings (loss) per common share	176,004	145,138	175,143	143,920
Shares used in calculation of diluted earnings (loss) per common share	176,004	147,097	175,143	143,920

Balance Sheet Data (unaudited):

	(amounts in thousands)	
	September 30, 2015	December 31, 2014
Cash and cash equivalents	46,355	70,933
Working capital	16,851	44,165
Total assets	63,132	92,287
Current portion of long-term debt	4,300	9,014
Long-term debt, less current portion	47,351	8,363
Total shareholders' equity (deficit)	(27,517)	38,478

Non-GAAP Reconciliations
(In thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
As reported - income (loss) from operations (GAAP)	$ (31,953)	$ 7,472	$ (90,463)	$ (46,859)
As reported - share-based compensation expense (GAAP)	5,888	3,837	12,997	17,022
As adjusted - income (loss) from operations (Non-GAAP)	$ (26,065)	$ 11,309	$ (77,466)	$ (29,837)

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