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Testo del comunicato

Vedi allegato.

CTI BIOPHARMA REPORTS SECOND QUARTER 2016 FINANCIAL RESULTS

SEATTLE, August 4, 2016-CTI BioPharma Corp. (NASDAQ and MTA:CTIC) today reported financial results for the second quarter ended June 30, 2016.

"The interest from oncologists generated by the Phase 3 PERSIST-1 long-term safety and efficacy results of pacritinib showing durable reduction in spleen volume and symptom burden including in patients that crossed over to pacritinib from best available therapy, presented at ASCO, supports our belief that pacritinib may play an important role in the treatment of myelofibrosis," said James A. Bianco, M.D., President and Chief Executive Officer of CTI BioPharma. "We are now in the process of preparing for the release of top-line results from the second Phase 3 trial of pacritinib, PERSIST-2, which we expect to report in the third quarter of 2016. The results from the full analysis of the PERSIST-2 trial are a key requirement as we continue to work with the FDA to seek to address their recommendations for getting pacritinib off clinical hold."

Second Quarter Event

In June 2016, researchers presented long-term safety and efficacy results from the pivotal Phase 3 trial, PERSIST-1, evaluating pacritinib versus best available therapy, excluding treatment with JAK2 inhibitors (BAT), in patients with myelofibrosis. As previously reported, the PERSIST-1 trial met its primary endpoint in the intent-to-treat population with statistically significant reduction in spleen volume when compared to patients receiving BAT. The results presented were an update on the efficacy and safety for all patients regardless of their initial platelet count, including patients with very low platelet counts at study entry, a condition known as severe or life-threatening thrombocytopenia. A planned analysis of the study up to 72 weeks demonstrated treatment with pacritinib led to durable reductions in spleen volume and symptom burden, two key measures of disease control, in patients with myelofibrosis, including patients with low platelets at baseline. These and other findings were presented at the 52nd Annual Meeting of the American Society of Clinical Oncology.

Second Quarter Financial Results

Total revenues for the second quarter and six months ended June 30, 2016, were $7.4 million and $43.8 million, respectively, compared to $1.1 million and $3.8 million for the respective periods in 2015. The increase in total revenue for the six month period in 2016 is primarily due to recognition of $32 million in milestone payments and reimbursement of development costs from Baxalta, which is now part of Shire plc, related to pacritinib. CTI BioPharma had previously received a cash advance for these milestone payments from Baxalta 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. Net product sales of PIXUVRI for the second quarter and the six months ended June 30, 2016, were $1.1 million and $2.3 million, respectively, compared to $0.8 million and $1.7 million for the respective periods in 2015.

GAAP operating loss for the second quarter and six months ended June 30, 2016, was $19.1 million and $14.9 million, respectively, compared to GAAP operating loss of $31.0 million and $58.5 million for the respective periods in 2015. Non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the second quarter and six months ended June 30, 2016, was $16.7 million and $8.8 million, respectively, compared to the non-GAAP operating loss of $28.3 million and $51.4 million for the respective periods in 2015. The decrease in CTI BioPharma's operating loss for the six month period ended June 30, 2016 is primarily due to recognition in the first quarter of 2016 of $32 million in milestone payments as license and contract revenue related to pacritinib as

mentioned above. Non-cash share-based compensation expense for the second quarter and six months ended June 30, 2016, was $2.3 million and $6.2 million, respectively, compared to $2.8 million and $7.1 million for the respective periods in 2015. For information on CTI BioPharma's use of non-GAAP operating loss and a reconciliation of such measure to GAAP operating loss, see the section below entitled "Non-GAAP Financial Measures."

Net loss for the second quarter of 2016 was $19.8 million, or ($0.07) per share, compared to a net loss of $32.6 million, or ($0.19) per share, for the same period in 2015. Net loss for the six months ended June 30, 2016 was $16.5 million, or ($0.06) per share, compared to a net loss of $61.2 million, or ($0.35) per share, for the same period in 2015. The decrease in net loss for the second quarter and the six months ended June 30, 2016 compared to the respective periods in 2015 is primarily due to increased net product sales and license and contract revenue and decreased operating expenses.

As of June 30, 2016, cash and cash equivalents totaled $76.7 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 CTI BioPharma 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. Where CTI BioPharma believes it may be beneficial, it intends to advance 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 non-GAAP financial measure of operating loss, excluding non-cash share-based compensation expense, for the second quarter and six months ended June 30, 2016 and June 30, 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 expense 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 operating loss in 2016 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 operating loss, 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 operating income or similarly titled measures. Accordingly, CTI BioPharma's non-GAAP operating loss 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 the 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 CTI BioPharma's intent to continue efforts to commercialize PIXUVRI in Europe 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Product sales, net	$ 1.051	$ 852	$ 2.274	$ 1.664
License and contract revenue	6.310	248	41.562	2.164
Total revenues	7.361	1.100	43.836	3.828
Operating costs and expenses:				
Cost of product sold	160	183	350	373
Research and development	16.697	19.320	37.543	36.791
Selling, general and administrative	9.571	12.624	20.883	24.921
Other operating expense	—	—	—	253
Total operating costs and expenses	26.428	32.127	58.776	62.338
Loss from operations	(19.067)	(31.027)	(14.940)	(58.510)
Non-operating expense:				
Interest expense	(677)	(597)	(1.391)	(1.091)
Amortization of debt discount and issuance costs	(38)	(131)	(139)	(311)
Foreign exchange loss	(236)	185	(38)	(543)
Other non-operating expense	(4)	(1.196)	(523)	(1.196)
Net loss before noncontrolling interest	(20.022)	(32.766)	(17.031)	(61.651)
Noncontrolling interest	256	170	577	458
Net loss	$ (19.766)	$ (32.596)	$ (16.454)	$ (61.193)
Basic and diluted net loss per common share	$ (0,07)	$ (0,19)	$ (0,06)	$ (0,35)
Shares used in calculation of basic and diluted net loss per common share	279.604	175.458	278.767	174.706

Balance Sheet Data (unaudited):

(amounts in thousands)

	June 30, 2016	December 31, 2015
Cash and cash equivalents	$ 76.707	$ 128.182
Working capital	48.152	62.566
Total assets	97.631	144.197
Current portion of long-term debt	7.498	37.371
Long-term debt, less current portion	15.375	19.124
Total shareholders' equity	36.755	47.413

Non-GAAP Reconciliations

(In thousands)

(unaudited)

	March 31,		March 31,	
	2016	2015	2016	2015
As reported - loss from operations (GAAP)	$ (19.067)	$ (31.027)	$ (14.940)	$ (58.510)
As reported - share-based compensation expense (GAAP)	2.331	2.773	6.157	7.109
As adjusted - loss from operations (Non-GAAP)	$ (16.736)	$ (28.254)	$ (8.783)	$ (51.401)

Fine Comunicato n.0696-57	Numero di Pagine: 8