

CTI BioPharma Reports Second Quarter 2019 Financial Results

August 1, 2019

SEATTLE, Aug. 1, 2019 /PRNewswire/ -- [CTI BioPharma Corp.](#) (Nasdaq: CTIC) today reported its financial results for the second quarter and six months ended June 30, 2019.

"We remain focused on advancing our development program for pacritinib in the U.S. for the treatment of myelofibrosis patients with severe thrombocytopenia," said Adam R. Craig, M.D., Ph.D., President and Chief Executive Officer of CTI BioPharma. "In June, we met with the U.S. Food and Drug Administration (FDA), and following that meeting, plan to evaluate the 200 mg twice-daily dose of pacritinib in the new PACIFICA Phase 3 trial. We have submitted for FDA review an amendment to the PAC203 protocol to allow a rapid transition to the PACIFICA Phase 3 trial, which we expect to initiate in the third quarter of 2019. In addition, based on multiple requests from physicians, in May we made the decision to undertake a pacritinib Expanded Access Program (EAP) for patients in the PAC203 trial. To facilitate this, we have extended the PAC203 trial to enable the patients to continue to receive uninterrupted treatment through the start of the EAP. In light of this change, we now intend to first report results from the PAC203 Phase 2 trial at a scientific conference before the end of the year."

Recent Updates

Following a Type B, End-of-Phase-2a meeting with the FDA in June, the Company announced that it plans to evaluate 200 mg of pacritinib administered twice daily (BID) compared to Physician's Choice in a Phase 3 trial of 180 patients with myelofibrosis and severe thrombocytopenia (platelet counts of less than 50,000 per microliter).

In July 2019, the Company submitted an amendment to the PAC203 trial protocol to allow a transition to the new PACIFICA Phase 3 trial. The Company plans to initiate the PACIFICA Phase 3 trial in the third quarter of 2019.

Expected 2019 Milestones

- Initiate PACIFICA Phase 3 trial of pacritinib in myelofibrosis patients with severe thrombocytopenia - Q3 2019
- Report safety and efficacy data from the PAC203 Phase 2 trial at a scientific conference before the end of 2019

Second Quarter Financial Results

License and contract revenues for the three and six months ended June 30, 2019 were \$0.4 million and \$1.1 million, respectively, compared to \$0.6 million and \$11.5 million for the respective periods in 2018. The decrease in license and contract revenues for the three months ended June 30, 2019 compared to the comparable period in 2018 is primarily due to a decrease in development services revenue from our partners Les Laboratoires Servier and Institut de Recherches Internationales Servier. The decrease in license and contract revenues for the six months ended June 30, 2019 compared to the same period in 2018 is primarily due to the recognition of \$10.0 million in milestone revenue in 2018 from Teva Pharmaceutical Industries Ltd. related to the achievement of a milestone for FDA approval of TRISENOX[®] (arsenic trioxide) for first-line treatment of acute promyelocytic leukemia. There were no such revenues for the comparable period in 2019.

Operating loss was \$11.0 million and \$21.5 million for the three and six months ended June 30, 2019, respectively, compared to operating loss of \$14.0 million and \$18.3 million for the respective periods in 2018. Operating loss during the three-month period ended June 30, 2019 as compared to the comparable period in 2018 resulted primarily from a decrease in research and development expenses. Operating loss for the six months ended June 30, 2019 as compared to the same period in 2018 resulted primarily from the decrease in license and contract revenues as mentioned above, as well as a decrease in research and development expenses.

Net loss attributable to common stockholders for the three months ended June 30, 2019 was \$11.0 million, or \$(0.19) for basic and diluted loss per share, compared to net loss attributable to common stockholders of \$11.3 million, or \$(0.20) for basic and diluted loss per share, for the same period in 2018. Net loss attributable to common stockholders for the six months ended June 30, 2019 was \$21.8 million, or \$(0.38) for basic and diluted loss per share, compared to net loss attributable to common stockholders of \$15.4 million, or \$(0.29) for basic and diluted loss per share, for the same period in 2018.

As of June 30, 2019, cash, cash equivalents and short-term investments totaled \$53.7 million, compared to \$67.0 million as of December 31, 2018.

About CTI BioPharma Corp.

CTI BioPharma Corp. is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers that offer a unique benefit to patients and their healthcare providers. In particular, we are focused on evaluating pacritinib for the treatment of adult patients with myelofibrosis. CTI BioPharma is headquartered in Seattle, Washington.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding our expectations regarding: our ability to commence the PACIFICA Phase 3 trial of pacritinib; the anticipated trial design and enrollment of the PACIFICA Phase 3 trial; the effectiveness of, and potential changes to, the PACIFICA Phase 3 trial design; the timing of, and results from, clinical trials and other development activities related to pacritinib, including the anticipated PACIFICA Phase 3 trial and its related protocol; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of pacritinib; and the anticipated timing of regulatory submissions and interactions, including FDA review of the amended PACIFICA Phase 3 protocol; our ability to successfully develop and achieve milestones in the development of pacritinib; and the anticipated benefits of pacritinib. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of pacritinib; the FDA may determine that the benefit/risk profile of pacritinib at the dose selected for the PACIFICA Phase 3 trial does not support approval based on the results of such trial, previously identified FDA concerns regarding safety and dosing limitations or otherwise; pacritinib may fail in development, may not receive required regulatory

approvals, or may be delayed to a point where it is not commercially viable; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; we may not achieve additional milestones in our pacritinib development program; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; adverse conditions in the general domestic and global economic markets; as well as the other risks identified in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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(tables follow)

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
License and contract revenues	\$ 416	\$ 613	\$ 1,056	\$ 11,459
Operating costs and expenses:				
Research and development	6,356	9,124	11,528	18,809
Selling, general and administrative	5,053	5,490	10,259	10,987
Restructuring expenses	—	—	794	—
Total operating costs and expenses	<u>11,409</u>	<u>14,614</u>	<u>22,581</u>	<u>29,796</u>
Loss from operations	(10,993)	(14,001)	(21,525)	(18,337)
Non-operating income (expense):				
Interest income	347	364	727	364
Interest expense	(269)	(297)	(563)	(585)
Amortization of debt discount and issuance costs	(130)	(130)	(260)	(264)
Foreign exchange gain (loss)	69	(1,575)	(169)	(852)
Other non-operating income	—	4,295	—	4,295
Total non-operating income (expense), net	<u>17</u>	<u>2,657</u>	<u>(265)</u>	<u>2,958</u>
Net loss before noncontrolling interest	(10,976)	(11,344)	(21,790)	(15,379)
Noncontrolling interest	5	8	5	22
Net loss	(10,971)	(11,336)	(21,785)	(15,357)
Deemed dividends on preferred stock	—	—	—	(80)
Net loss attributable to common stockholders	<u>\$ (10,971)</u>	<u>\$ (11,336)</u>	<u>\$ (21,785)</u>	<u>\$ (15,437)</u>
Basic and diluted net loss per common share	<u>\$ (0.19)</u>	<u>\$ (0.20)</u>	<u>\$ (0.38)</u>	<u>\$ (0.29)</u>
Shares used in calculation of basic and diluted net loss per common share:	<u>57,973</u>	<u>57,941</u>	<u>57,973</u>	<u>54,148</u>

Balance Sheet Data (unaudited):

	(amounts in thousands)	
	June 30, 2019	December 31, 2018
Cash and cash equivalents	\$ 35,364	\$ 36,439
Short-term investments	18,297	30,599
Working capital	38,653	59,437
Total assets	66,243	89,832
Current portion of long-term debt	4,812	4,812
Long-term debt, less current portion	6,861	9,267
Total stockholders' equity	34,985	52,939



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