

CTI BioPharma Reports Fourth Quarter and Full Year 2019 Financial Results

March 12, 2020

SEATTLE, March 12, 2020 /PRNewswire/ -- CTI BioPharma Corp. (Nasdaq: CTIC) today reported its financial results for the fourth quarter and full year ended December 31, 2019.

"In the latter half of 2019 and beginning of 2020, we further advanced our pacritinib development program, including presenting data at the American Society of Hematology Annual Meeting that reinforced the clinical and scientific rationale for our ongoing PAC203 Phase 3 PACIFICA trial evaluating pacritinib at 200 mg BID in severely thrombocytopenic myelofibrosis patients," said Adam R. Craig, M.D., Ph.D. "Severely thrombocytopenic myelofibrosis patients have limited, and often ineffective, therapeutic options. In an effort to advance pacritinib as quickly as possible to these patients, we established an accelerated approval pathway with the U.S. Food and Drug Administration ("FDA") by amending the PACIFICA pivotal Phase 3 trial protocol to allow for the primary analysis of Spleen Volume Reduction ("SVR") rates on the first 168 patients, with an end-of-study analysis of Total Symptom Score ("TSS") and Overall Survival ("OS") following the full enrollment of 348 patients. If the primary endpoint of SVR is met following the planned review of data from the first 168 patients, we intend to submit a New Drug Application ("NDA") under the FDA's subpart H regulations. We expect to report primary SVR data by the end of 2021, with a potential NDA filing in early 2022. Additionally, we recently raised an additional \$59.3 million in a rights offering, which provides us with additional cash runway into Q1 2022 as we continue to develop pacritinib."

Fourth Quarter Financial Results

Operating loss was \$9.5 million and \$40.7 million for the three months and year ended December 31, 2019, respectively, compared to operating income of \$0.2 million and operating loss of \$32.9 million for the respective periods in 2018. The operating loss during the three-month period ended December 31, 2019 as compared to the operating income for the comparable period in 2018 resulted primarily from the decrease in license and contract revenue as discussed below, partially offset by a decrease in operating expenses. The increase in operating loss for the year ended December 31, 2019 as compared to the same period in 2018 resulted primarily from a decrease in license and contract revenues between periods as discussed below, partially offset by a decrease in operating expenses. As of December 31, 2019, cash, cash equivalents and short-term investments totaled \$33.7 million, compared to \$67.0 million as of December 31, 2018. In March 2020, we completed our rights offering and received approximately \$59.3 million in net proceeds. We expect current cash, cash equivalents and short-term investments, when combined with the net proceeds we received from the rights offering, will enable us to fund our operations into the first quarter of 2022.

License and contract revenues for the three months ended December 31, 2018 were \$14.1 million while no revenues were recognized during the three months ended December 31, 2019. License and contract revenues for the three months ended December 31, 2018 were primarily related to milestone revenues recognized upon the achievement of a regulatory milestone under the license and collaboration agreement for PIXUVRI® with Les Laboratoires Servier and Institut de Recherches Internationales Servier as well as the attainment of a worldwide net sales milestone of TRISENOX® (arsenic trioxide) under the agreement with Teva Pharmaceutical Industries Ltd. ("Teva"). License and contract revenues for the years ended December 31, 2019 and 2018 were \$3.3 million and \$26.3 million, respectively. The decrease between periods primarily resulted from milestone revenues recognized in 2018 from Teva related to the achievement of a milestone for FDA approval of TRISENOX for first-line treatment of acute promyelocytic leukemia, in addition to the license and contract revenues recognized during the three months ended December 31, 2018, as discussed above.

Net loss attributable to common stockholders for the three months ended December 31, 2019 was \$8.2 million, or \$(0.14) for basic and diluted loss per share, compared to net income attributable to common stockholders of \$0.8 million, or \$0.01 for basic and diluted income per share, for the same period in 2018. Net loss attributable to common stockholders for the year ended December 31, 2019 was \$40.0 million, or \$(0.69) for basic and diluted loss per share, compared to net loss attributable to common stockholders of \$29.4 million, or \$(0.52) for basic and diluted loss per share, for the same period in 2018.

About CTI BioPharma Corp.

We are 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. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis. We are headquartered in Seattle, Washington.

Forward-Looking Statements

Statements included in this press release that are not historical in nature are 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 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 include, but are not limited to: our ability to conduct and complete clinical trials in our currently anticipated timeframes; our ability to successfully demonstrate the safety and efficacy of pacritinib; our expectations regarding the completion and outcome of the PACIFICA Phase 3 trial; the risk that 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; the risk that pacritinib may fail in development; our ability to submit an NDA for pacritinib in the timeline currently anticipated; our ability to receive regulatory approval for pacritinib pursuant to the accelerated approval pathway or at all; the risk that pacritinib may be delayed to a point where it is not commercially viable; the accuracy of our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations; and those risks more fully discussed in the section entitled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019. 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 December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
License and contract revenues	\$ —	\$ 14,108	\$ 3,345	\$ 26,290
Operating costs and expenses:				
Research and development	4,981	7,928	24,107	36,467
Selling, general and administrative	4,493	5,312	19,155	22,062
Restructuring expenses	—	660	794	660
Total operating costs and expenses	9,474	13,900	44,056	59,189
(Loss) income from operations	(9,474)	208	(40,711)	(32,899)
Non-operating income (expense):				
Interest income	169	419	1,172	1,219
Interest expense	(199)	(316)	(1,002)	(1,209)
Amortization of debt discount and issuance costs	(130)	(131)	(521)	(525)
Foreign exchange gain (loss)	128	665	(281)	(233)
Other non-operating income	1,320	—	1,320	4,295
Total non-operating income, net	1,288	637	688	3,547
Net (loss) income before noncontrolling interest	(8,186)	845	(40,023)	(29,352)
Noncontrolling interest	(2)	1	3	32
Net (loss) income	(8,188)	846	(40,020)	(29,320)
Deemed dividends on preferred stock	—	—	—	(80)
Net (loss) income attributable to common stockholders	\$ (8,188)	\$ 846	\$ (40,020)	\$ (29,400)
Net (loss) income per common share:				
Basic	\$ (0.14)	\$ 0.01	\$ (0.69)	\$ (0.52)
Diluted	\$ (0.14)	\$ 0.01	\$ (0.69)	\$ (0.52)
Shares used in calculation of (loss) income per common share:				
Basic	57,974	57,969	57,974	56,073
Diluted	57,974	57,970	57,974	56,073

Balance Sheet Data (unaudited):

	(amounts in thousands)	
	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 31,144	\$ 36,439
Short-term investments	2,522	30,599
Working capital	17,092	59,437
Total assets	46,280	89,832
Current portion of long-term debt	4,812	4,812
Long-term debt, less current portion	4,455	9,267
Total stockholders' equity	17,930	52,939



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