Curis Reports Fourth Quarter and Year-End 2019 Financial Results and Provides Business Update

- Prioritizing resources for CA-4948 and CI-8993 clinical development programs -
- Discontinuing fimepinostat-venetoclax combination study -
- Management to host conference call today at 4:30 p.m. ET -

LEXINGTON, Mass., March 19, 2020 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today reported its financial results for the fourth quarter and year ended December 31, 2019.

"Our mission at Curis is to develop the next generation of targeted cancer therapies that improve the lives of patients. In 2019, we made significant clinical progress across our pipeline, including reporting preliminary data for CA-4948 that demonstrates anti-cancer activity," said James Dentzer, President and Chief Executive Officer of Curis. "We look forward to reporting additional clinical data on CA-4948 later this year. In 2019, we also reported initial data in our Phase 1 study of fimepinostat in combination with venetoclax, in which we observed no significant drug-drug interaction. Since then, we have enrolled additional patients and have not seen an efficacy signal that would warrant further development in this indication. Given current market conditions, we have made the decision to discontinue the study and focus our resources on CA-4948 and CI-8993. We would like to thank the patients and their families who participated in this study as well as our investigators and employees for their commitment and support."

Mr. Dentzer continued: "On the corporate side, we are pleased to have entered into a common stock purchase agreement with Aspire Capital, which provides us with a flexible and efficient source of capital to advance our clinical programs. We are also excited about the recent execution of several collaborations and partnerships, including the option and license agreement for CI-8993, our clinical anti-VISTA candidate. We look forward to initiating a Phase 1a/1b study of CI-8993 and reporting data from our ongoing study of CA-4948 later this year."

Full Year 2019 and Recent Operational Highlights

Precision oncology, CA-4948 (IRAK4 Inhibitor; Aurigene collaboration):

In December 2019, Curis announced updated preliminary data from its ongoing Phase 1 dose escalation study of CA-4948, an IRAK4 kinase inhibitor, for the treatment of patients with R/R non-Hodgkin's lymphoma (NHL), including patients with DLBCL, Waldenström's macroglobulinemia (WM) and oncogenic MYD88 mutations. The data demonstrated anti-cancer activity and a favorable safety profile for CA-4948, establishing that targeting IRAK4 may be a viable clinical strategy. Curis plans to continue dose escalation in this Phase 1 study until the maximum tolerated dose and/or recommended Phase 2 dose of CA-4948 is determined.

Precision oncology, fimepinostat (HDAC/PI3K inhibitor):

Today, Curis announced that it is discontinuing its Phase 1 study of fimepinostat, in combination with venetoclax, a BCL-2 inhibitor, in relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), including double-hit/double-expressor (DH/DE) lymphoma. Ongoing analytical research with DarwinHealth to characterize biomarkers and tumor subtype alignments will help guide any future clinical development opportunities with fimepinostat.

Immuno-oncology, CI-8993 (anti-VISTA antibody; ImmuNext collaboration):

In January 2020, Curis announced it entered into an option and license agreement to acquire exclusive, worldwide rights from ImmuNext Inc. (ImmuNext) to develop and commercialize anti-VISTA antibodies for the treatment of cancer, including ImmuNext's lead compound, CI-8993. CI-8993 is a clinical-stage monoclonal antibody designed to antagonize the V-domain Ig suppressor of T-cell activation (VISTA) signaling pathway.

Corporate:

In February 2020, Curis entered into a common stock purchase agreement of up to $30 million with Aspire Capital Fund, LLC (Aspire Capital). Under the terms of the Agreement, Aspire Capital made an initial investment via purchase of $3 million of common shares of Curis. In addition, Aspire committed to purchasing up to an additional $27 million of common shares of Curis at Curis' request from time to time during a 30-month period, at prices based on the market price at the time of each sale, subject to certain limits.
In February 2020, Curis entered into an amendment of its collaboration, license and option agreement with Aurigene Discovery Technologies, Ltd. (Aurigene), under which Aurigene will fund and conduct a Phase 2b/3 randomized study evaluating CA-170, an orally available, dual inhibitor of VISTA and PDL1, in combination with chemoradiation, in approximately 240 patients with non-squamous non-small cell lung cancer. In turn, Aurigene received rights to develop and commercialize CA-170 in Asia, in addition to its existing rights in India and Russia. Curis retained U.S., E.U., and rest of world rights to CA-170, and is entitled to receive royalty payments on potential future sales of CA-170 in Asia.
In January 2020, Curis and DarwinHealth, Inc. announced a multi-year scientific research collaboration to characterize biomarkers and tumor subtype alignments to identify potential additional therapeutic opportunities for fimepinostat.

Upcoming 2020 Planned Milestones

Continue dose escalation of CA-4948 in the ongoing Phase 1 study to determine the recommended Phase 2 dose and report updated efficacy data from the study in 2020
Initiate a Phase 1 study of CA-4948 in patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), including patients with spliceosome mutations that encode oncogenic IRAK4-L in the first half of 2020
Initiate a Phase 1a/1b dose escalation study of CI-8993 in in the second half of 2020.

Full Year and Fourth Quarter 2019 Financial Results

For the year ended December 31, 2019, Curis reported a net loss of $32.1 million, or $0.97 per share on both a basic and diluted basis, as compared to a net loss of $32.6 million, or $0.98 per share on both a basic and diluted basis in 2018. For the fourth quarter of 2019, Curis reported a net loss of $8.6 million or $0.26 per share on both a basic and diluted basis, as compared to a net loss of $5.9 million, or $0.18 per share on both a basic and diluted basis for the same period in 2018.

Revenues for the year ended December 31, 2019, were $10.0 million as compared to $10.4 million for the same period in 2018. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the fourth quarters of 2019 and 2018 were $3.3 million and $2.8 million, respectively.

Operating expenses for the year ended December 31, 2019 were $34.4 million as compared to $39.8 million for the same period in 2018. Operating expenses for the fourth quarter of 2019 were $10.6 million, as compared to $7.9 million for the same period in 2018, and comprised the following:

Costs of Royalty Revenues. Costs of royalty revenues, primarily amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were $0.5 million for the year ended December 31, 2019 as compared to $0.6 million for the same period in 2018. Cost of royalty revenues were $0.2 million for the fourth quarter of 2019, as compared to $0.1 million for the same period in 2018.

Research and Development Expenses. Research and development expenses were $22.3 million for the year ended December 31, 2019, as compared to $24.4 million for the same period in 2018. The decrease was primarily due to lower employee related expenses which resulted from a headcount reduction in the fourth quarter of 2018. This decrease was partially offset by increased clinical, manufacturing and consulting costs for the Company's ongoing Phase 1 clinical trials. Research and development expenses were $7.5 million for the fourth quarter of 2019 as compared to $4.7 million for the same period in 2018. The increase was primarily due to increased costs related to clinical activities and manufacturing costs for fimepinostat and CA-4948.

General and Administrative Expenses. General and administrative expenses were $11.6 million for the year ended December 31, 2019, as compared to $14.8 million for the same period in 2018. The decrease was primarily due to lower personnel and stock-based compensation expense combined with lower legal and professional service expense. General and administrative expenses were $3.0 million for both the fourth quarter of 2019 and 2018 respectively.

Other expense, net. Net other expense was $7.8 million for the year ended December 31, 2019, as compared to $3.2 million for the same period in 2018. Net other expense primarily consisted of the $3.5 million loss on extinguishment of debt in conjunction with the March 2019 repayment of the loan obligation to HealthCare Royalty Partners, and imputed interest of $4.1 million resulting from the previously announced sale of a portion of Erivedge royalties to Oberland Capital Management. For the fourth quarter of 2019 and 2018, net other expense was $1.3 million and $0.8 million respectively.

As of December 31, 2019, Curis's cash, cash equivalents, marketable securities and investments totaled $20.5 million and there were approximately 33.2 million shares of common stock outstanding. Curis expects that its existing cash, cash equivalents and investments should enable it to maintain its planned operations into the second half of 2020.

Conference Call Information

Curis management will host a conference call today, March 19, 2020, at 4:30 p.m. ET, to discuss these financial results, as well as provide a corporate update.

To access the live conference call, please dial 1-888-346-6389 from the United States or 1-412-317-5252 from other locations, shortly before 4:30 p.m. ET. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Curis, Inc.

Curis is a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer. In 2015, Curis entered into a collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of immune checkpoints including, the VISTA/PDL1 antagonist CA-170, and the TIM3/PDL1 antagonist CA-327, as well as the IRAK4 kinase inhibitor, CA-4948. CA-4948 is currently undergoing testing in a Phase 1 trial in patients with non-Hodgkin lymphoma. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are

commercializing Erivedge® for the treatment of advanced basal cell carcinoma. For more information, visit Curis' website at www.curis.com.

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including without limitation statements regarding the Company's planned prioritization of resources, its plans to continue dose escalation in the Phase 1 trial of CA-4948 and to report efficacy data from the trial in 2020, its plan to initiate a Phase 1 trial of 4948 in AML and MDS in the first half of 2020, its plans to initiate a Phase 1a/1b trial of CI-8993 in the second half of 2020, the period in which Curis expects that its existing cash, cash equivalents and investments will enable it to fund its operations, its ability to access financing under its purchase agreement with Aspire, statements with respect to the plans, strategies and objectives of management for future operations, and the Company's expectations regarding the potential therapeutic benefit of its proprietary drug candidates. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "will," "may," "could" or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other important factors that may cause actual results to be materially different from those indicated by such forward-looking statements. For example, Curis may experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreements with Aurigene and ImmuNext will continue for their full terms, that Curis or its collaborators will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge in BCC. Erivedge may not demonstrate sufficient or any activity to merit its further development in disease indications other than BCC. Competing drugs may be developed that are superior to Erivedge. In connection with its agreement with Oberland Capital, Curis faces risks relating to the transfer and encumbrance of certain royalty and royalty-related payments on commercial sales of Erivedge, including the risk that, in the event of a default by Curis or its wholly-owned subsidiary, Curis could lose all retained rights to future royalty and royalty-related payments, Curis could be required to repurchase such future royalty and royalty-related payments at a price that is a multiple of the payments it has received, and its ability to enter into future arrangements may be inhibited, all of which could have a material adverse effect on its business, financial condition and stock price. Curis will require substantial additional capital to fund its business. Based on its available cash resources, it does not have sufficient cash on hand to support current operations within the next 12 months from the date of this press release. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate some of its research and development programs, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, any of its product candidates, which could adversely affect its business prospects and its ability to continue operations, and would have a negative impact on its financial condition and its ability to pursue its business strategies. If it is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its audited financial statements, and it is likely that investors will lose all or a part of their investment. Curis faces substantial competition. Curis also faces risks relating to potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time-consuming patent litigation and interference proceedings. Unstable market and economic conditions , natural disasters, public health crises, political crises and other events outside of Curis's control could significantly disrupt its operations or the operations of third parties on which Curis depends, and could adversely impact Curis's operating results and its ability to raise capital. For example, the recent outbreak of the novel coronavirus may result in closures of third party facilities, impact enrollment in Curis's ongoing or planned clinical trials or impact sales of Erivedge by Genentech and/or Roche. The extent to which the coronavirus may impact Curis's business or operating results is uncertain. Important factors that may cause or contribute to actual results being materially different from those indicated by forward-looking statements include the factors set forth under the caption "Risk Factors" in our most recent Form 10-K and Form 10-Q and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission ("SEC"). In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis's views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by law.

CURIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)
(In thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2019	2018	2019	2018
Revenues, net:				
Royalties	$ 3,233	$ 2,772	$ 10,418	$ 10,421
Contra revenue, net	54	(17)	(414)	7
Total revenues, net:	3,287	2,755	10,004	10,428
Operating expenses:				
Costs of royalty revenues	161	146	503	563
Research and development	7,461	4,713	22,302	24,413
General and administrative	2,999	3,044	11,555	14,785
Total operating expenses	10,621	7,903	34,360	39,761
Net loss from operations	(7,334)	(5,148)	(24,356)	(29,333)
Loss on debt extinguishment	—	—	(3,495)	—
Interest income	101	143	614	684
Imputed interest expense related to the sale of future royalties	(1,334)	—	(4,055)	—
Interest expense, debt	—	(936)	(791)	(3,926)
Other income (expense), net	(42)	—	(58)	—
Other expense, net	(1,275)	(793)	(7,785)	(3,242)
Net loss	(8,609)	(5,941)	(32,141)	(32,575)
Basic and diluted net loss per common share	$ (0.26)	$ (0.18)	$ (0.97)	$ (0.98)
Basic and diluted weighted average common shares outstanding	33,209,217	33,121,666	33,180,516	33,118,393

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	December 31, 2019	December 31, 2018
ASSETS		
Cash, cash equivalents and investments	$ 20,543	$ 24,270
Restricted cash	969	153
Accounts receivable	3,244	2,864
Property and equipment, net	154	267
Operating lease right-of-use asset	149	—
Goodwill	8,982	8,982
Other assets	1,066	829
Total assets	$ 35,107	$ 37,365
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable, accrued expenses and other liabilities	$ 6,375	$ 6,377
Operating lease liability	166	—
Debt obligations, net	—	35,484
Liability related to the sale of future royalties, net	62,477	—
Total liabilities	69,018	41,861
Total stockholders' deficit	(33,911)	(4,496)
Total liabilities and stockholders' deficit	$ 35,107	$ 37,365

SOURCE Curis, Inc.

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https://investors.curis.com/2020-03-19-Curis-Reports-Fourth-Quarter-and-Year-End-2019-Financial-Results-and-Provides-Business-Update