Curis Reports Fourth Quarter and Year-End 2020 Financial Results

- Significantly expanded IRAK4 inhibitor CA-4948 development to include Phase 1 CA-4948 monotherapy study in acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), Phase 1 CA-4948/ibrutinib combination study in patients with relapsed or refractory (R/R) hematologic malignancies, Phase 2 LUCAS Investigator Sponsored Trial (IST) for the treatment of anemia in lower-risk MDS patients, and Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) -
- Presented CA-4948 Phase 1 data showing broad clinical activity in patients with R/R AML and MDS and Phase 1 data in patients with R/R non-Hodgkin's lymphoma (NHL) showing durable and dose-dependent reductions in tumor burden -
- Raised $169.6M of gross proceeds in December 2020 public offering; extending cash runway into 2024 -
- Multiple data readouts expected in 2021 from CA-4948 and anti-VISTA antibody CI-8993 clinical trials -
- Management to host conference call today at 4:30 p.m. ET -

LEXINGTON, Mass., March 16, 2021 /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, 2020.

"2020 was a transformative year for Curis, as we made significant progress in our mission to develop the next generation of targeted cancer therapies that meaningfully improve and extend the lives of patients. Despite the difficulties and uncertainty brought about by the ongoing coronavirus pandemic, we significantly advanced and expanded each program in our clinical pipeline, headlined by the very encouraging data from our Phase 1 trials of lead asset, CA-4948, presented in December in conjunction with ASH," said James Dentzer, President and Chief Executive Officer of Curis. "We look forward to providing additional updates on our IRAK4 program throughout the year, with clinical data readouts from our ongoing studies, including the CA-4948 monotherapy study in AML/MDS and the CA-4948/ibrutinib combination study for patients with R/R hematologic malignancies that we initiated in early 2021. We also continue to enroll patients and bring additional trial sites online in our Phase 1a/1b trial of CI-8993, our first-in-class monoclonal anti-VISTA antibody for the treatment of patients with R/R solid tumors, and look forward to providing preliminary data from this exciting study later this year."

Mr. Dentzer continued, "2020 was also a pivotal year on the corporate side for Curis. Through the execution of several key financings and partnerships, we have the resources needed to advance our programs through their next data catalysts, while also providing us the ability to invest efficiently in our pipeline of first-in-class cancer therapeutics. We are excited about the opportunities stemming from our Q4 signing of the CRADA with the NCI in addition to the recently announced Phase 2 IST of CA-4948 for the treatment of anemia in patients with lower-risk MDS led by Dr. Uwe Platzbecker at Universität Leipzig. These new partnerships provide powerful validation of our IRAK4 platform and allow us to leverage the resources of premier research organizations to significantly expand the reach of our clinical and preclinical programs."

Fourth Quarter 2020 and Recent Operational Highlights

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

In December 2020, Curis announced positive preliminary data from its ongoing Phase 1 study of CA-4948 monotherapy in patients with R/R AML and high-risk MDS, including marrow blast reductions observed in all evaluable patients and 2 of 6 evaluable patients experiencing a marrow complete response. Curis continues to enroll patients, is currently enrolling in the 500mg BID dose cohort of the study and expects to report additional data in mid-year 2021.
In December 2020, Curis provided updated preliminary data from its ongoing Phase 1 study of CA-4948 showing durable and dose-dependent reductions in tumor burden in patients with R/R NHL and announced the recommended Phase 2 dose, in addition to the identification of two potentially predictive biomarkers demonstrating target engagement and potential for patient enrichment, in an oral presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition.
In February 2021, Curis announced the dosing of the first patient in its Phase 1 dose-escalation and expansion study of CA-4948, an IRAK4 kinase inhibitor, and the BTK inhibitor, ibrutinib, for the treatment of patients with relapsed or refractory hematologic malignancies. In preclinical models, CA-4948 demonstrated synergistic anti-cancer activity when combined with a potent BTK inhibitor such as ibrutinib.

Approximately 18 patients will be enrolled in the dose-escalation portion and will receive starting dose and escalation doses that have been observed to be safe and effective, combined with ibrutinib doses appropriate for their respective NHL subtype.
The primary endpoints of Part 1 will be determination of maximum tolerated dose (MTD), and the recommended Phase 2 dose (RP2D).
Part 2 of the study will enroll patients across a basket of four cohorts:

Marginal zone lymphoma (MZL)
Activated B-cell subtype of Diffuse Large B-cell Lymphoma (ABC-DLBCL)
Primary central nervous system lymphoma (PCNSL)

NHL with adaptive ibrutinib resistance.

An interim futility analysis will be conducted after approximately 15-20 patients are enrolled in each cohort. Primary endpoints of Part 2 will be complete response or objective response rate and duration of response. Curis expects to report initial data from the study in the fourth quarter of 2021.

In February 2021, Curis announced the initiation of the investigator-sponsored Phase 2 LUCAS trial of CA-4948 for the treatment of anemia in patients with very low, low, or intermediate-risk MDS. The trial is expected to start recruitment in the second quarter of 2021 and is expected to enroll 84 patients across two cohorts:

Cohort A: Erythropoiesis stimulating agent (ESA) refractory/intolerant patients
Cohort B: ESA naïve patients with transfusion dependence (min. 20 patients) or transfusion independence (min. 20 patients)

Patients in both cohorts will receive 300mg CA-4948 twice-daily (BID) for 21 days in at least four repeating cycles lasting 28 days each.

The primary endpoint of the study is to evaluate the proportion of patients that develop an erythroid response (HI-E) according to IWG 2018 criteria.

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

In November 2020, Curis published trial design details from its ongoing Phase 1a/1b dose-escalation study of its first-in-class monoclonal anti-VISTA antibody for the treatment of R/R solid tumors.
Curis continues to enroll patients in the study and expects to report initial safety and efficacy data in the second half of 2021.

Corporate:

In December 2020, Curis closed an underwritten public offering of 29,500,000 shares of its common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 3,847,826 shares, raising gross proceeds of approximately $169.6 million before deducting underwriting discounts and commissions and offering expenses.
In November 2020, Curis entered into a CRADA with the NCI. Under the CRADA, Curis will collaborate with the NCI Experimental Therapeutics Program (NExT) and the NCI Cancer Therapy Evaluation Program to conduct non-clinical and clinical studies of Curis' proprietary compound, CA-4948, an IRAK4 kinase inhibitor that acts as a Toll-like Receptor (TLR) suppressor, as an anti-cancer agent.

Upcoming 2021 Planned Milestones

Report additional clinical data from the Phase 1 study of CA-4948 in patients with AML and high-risk MDS, including patients with spliceosome mutations that encode oncogenic IRAK4-L in mid-year 2021.
Report additional clinical biomarker data gathered in the Phase 1 study of CA-4948 in patients with R/R NHL in mid-year 2021.
Announce initial safety and efficacy data from the ongoing Phase 1 study of CA-4948 in combination with ibrutinib in patients with R/R NHL in the second half of 2021.
Report initial safety and efficacy data from the ongoing Phase 1a/1b dose-escalation study of CI-8993 for the treatment of R/R solid tumors in the second half of 2021.

Full Year and Fourth Quarter 2020 Financial Results

For the year ended December 31, 2020, Curis reported a net loss of $29.9 million, or $0.61 per share on both a basic and diluted basis, as compared to a net loss of $32.1 million, or $0.97 per share on both a basic and diluted basis in 2019. For the fourth quarter of 2020, Curis reported a net loss of $7.5 million or $0.11 per share on both a basic and diluted basis, as compared to a net loss of $8.6 million, or $0.26 per share on both a basic and diluted basis for the same period in 2019.

Revenues for the year ended December 31, 2020, were $10.8 million as compared to $10.0 million for the same period in 2019. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the fourth quarters of 2020 and 2019 were $3.0 million and $3.3 million, respectively.

Operating expenses for the year ended December 31, 2020 were $35.7 million as compared to $34.4 million for the same period in 2019. Operating expenses for the fourth quarter of 2020 were $9.3 million, as compared to $10.6 million for the same period in 2019, 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 years ended December 31,

2020 and 2019. Cost of royalty revenues were $0.2 million for the fourth quarter of 2020 and 2019.

Research and Development Expenses. Research and development expenses were $23.1 million for the year ended December 31, 2020, as compared to $22.3 million for the same period in 2019. Research and development expenses were $5.6 million for the fourth quarter of 2020 as compared to $7.5 million for the same period in 2019. The decrease was primarily due to a decrease in clinical and manufacturing costs related to CA-170 and fimepinostat.

General and Administrative Expenses. General and administrative expenses were $12.1 million for the year ended December 31, 2020, as compared to $11.6 million for the same period in 2019. General and administrative expenses were $3.5 million for the fourth quarter of 2020, as compared to $3.0 million for the same period in 2019. The increase was primarily due to an increase in personnel related costs.

Other Expense, Net. Net other expense was $5.0 million for the year ended December 31, 2020, as compared to $7.8 million for the same period in 2019. For the fourth quarter of 2020 and 2019, net other expense was $1.2 million and $1.3 million, respectively. Net other expense primarily consisted of imputed interest expense related to future royalty payments.

As of December 31, 2020, Curis's cash, cash equivalents and investments totaled $183.1 million, and there were approximately 91.5 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 2024.

Conference Call Information

Curis management will host a conference call today, March 16, 2021, 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 in patients with non-Hodgkin's lymphoma both as a monotherapy and in combination the with BTK inhibitor ibrutinib. Curis is also evaluating CA-4948 in a Phase 1 trial in patients with acute myeloid leukemia and myelodysplastic syndromes. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody, which is currently undergoing testing in a Phase 1a/1b trial in patients with solid tumors. 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 any expectations of the potential for the Company's proprietary drug candidates, including the potential developments of any clinical biomarker data, statements with respect to the timing of the Company's studies, including enrollment and reporting of data, and any statements with respect to the LUCAS IST, the CRADA with NCI, and the Company's ability to advance and broaden its clinical programs. 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. 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. 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 COVID-19 pandemic may result in closures of third-party facilities, impact enrollment in clinical trials or impact sales of Erivedge by Genentech and/or Roche. The extent to which the COVID-19 pandemic may impact Curis's business or operating results is uncertain. Other 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,***	
	2020	***2019***	***2020***	***2019***
Revenues, net:				
Royalties	$ 3,043	$ 3,233	$ 10,724	$ 10,418
Other revenue	4	—	214	—
Contra revenue, net	(23)	54	(103)	(414)
Total revenues, net:	3,024	3,287	10,835	10,004
Operating expenses:				
Costs of royalties	151	161	534	503
Research and development	5,609	7,461	23,068	22,302
General and administrative	3,539	2,999	12,131	11,555
Total costs and expenses	9,299	10,621	35,733	34,360
Loss from operations	(6,275)	(7,334)	(24,898)	(24,356)
Loss on debt extinguishment	—	—	—	(3,495)
Interest income	4	101	63	614
Imputed interest expense related to the sale of future royalties	(1,246)	(1,334)	(5,095)	(4,055)
Interest expense, debt	—	—	—	(791)
Other income (expense), net	—	(42)	22	(58)
Total other expense	(1,242)	(1,275)	(5,010)	(7,785)
Net loss	(7,517)	(8,609)	(29,908)	(32,141)
Basic and diluted net loss per common share	$ (0.11)	$ (0.26)	$ (0.61)	$ (0.97)
Basic and diluted weighted average common shares outstanding	66,363,229	33,209,217	48,670,381	33,180,516

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	December 31, 2020	*December 31, 2019*
ASSETS		
Cash, cash equivalents and investments	$ 183,058	$ 20,543
Restricted cash	816	969
Accounts receivable	3,043	3,244
Property and equipment, net	663	154
Operating lease right-of-use asset	6,578	149
Goodwill	8,982	8,982
Other assets	1,218	1,066
Total assets	$ 204,358	$ 35,107
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable, accrued liabilities and other liabilities	$ 7,791	$ 6,375
Operating lease liability	6,771	166
Debt obligations	891	—
Liability related to the sale of future royalties, net	58,235	62,477
Total liabilities	73,688	69,018
Total stockholders' equity (deficit)	130,670	(33,911)
Total liabilities and stockholders' equity (deficit)	$ 204,358	$ 35,107

SOURCE Curis, Inc.

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