Curis Reports Third Quarter 2021 Financial Results and Business Update

Enrolled first patient in Phase 1 Study of CA-4948 combination therapy in patients with Relapsed or Refractory Acute Myeloid Leukemia or Myelodysplastic Syndromes
Presented additional preclinical data for CA-4948 demonstrating potential in additional hematologic malignancies at AACR-NCI-EORTC Virtual Conference on Molecular Targets and Cancer Therapeutics
Abstract accepted for CI-8993 at Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting
Clinical Data Update Call to be held in January to discuss updated data from ongoing studies, including the Phase 1/2 monotherapy study of CA-4948 in AML/MDS patients with spliceosome or FLT3 mutation
Management to host conference call today at 4:30 p.m. ET

LEXINGTON, Mass., Nov. 9, 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 third quarter ended September 30, 2021 and provided business updates.

"During the third quarter of 2021, we continued to advance our clinical trials of CA-4948, our first-in-class, small molecule IRAK4 inhibitor in nine distinct patient populations across AML, MDS and B cell cancers, including the recent initiation of our Phase 1 combination study in AML/MDS. At the AACR-NCI-EORTC Conference in October, we shared exciting preclinical data highlighting potential applications for CA-4948 across different hematologic malignancies, including pCNS lymphoma, an aggressive lymphoma with severe unmet need for patients, further highlighting the potential broad applicability of CA-4948," said James Dentzer, President and Chief Executive Officer of Curis.

"As we look ahead, we plan to provide a clinical data update in January from our ongoing clinical studies, including safety data from our Phase 1 study of CI-8993 and the latest safety and efficacy data from our CA-4948 study in AML/MDS patients with spliceosome or FLT3 mutations."

"In our ongoing monotherapy AML/MDS study, we expect to achieve our enrollment target of having 10-20 total patients with a spliceosome mutation by year-end. We believe data from these patients may provide for an opportunity to explore discussions with the FDA on a registrational path forward in the first half of 2022," concluded Mr. Dentzer.

Third Quarter 2021 and Recent Operational Highlights

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

- Enrollment remains on track in nine distinct patient populations across AML, MDS and B cell cancers.
  In November 2021, Curis initiated dosing in the combination stage of the Phase 1/2 study of CA-4948 plus azacitidine and CA-4948 plus venetoclax.
  - The combination therapy portion includes two arms: CA-4948 plus azacitidine, for patients naïve to HMA, and CA-4948 plus venetoclax, for patients naïve to venetoclax.
    When combined with azacitidine, CA-4948 will be dosed at 200 mg twice daily for 21 days of a 28-day cycle, followed by a 300 mg dose cohort if tolerability allows. Azacitidine will be given in 7 consecutive doses or split doses starting at 75 mg/m^2.
    When combined with venetoclax, the starting dose level for CA-4948 will be 200 mg twice daily for 21 days of a 28-day cycle, followed by a 300 mg dose cohort if tolerability allows. Venetoclax will be administered at 100 mg orally with a ramp up over 3 days to 400 mg for 21 days of a 28-day cycle.
- In October 2021, Curis announced new preclinical data highlighting the potential of CA-4948 in additional hematologic malignancies in two presentations at the AACR-NCI-EORTC Virtual Conference on Molecular Targets and Cancer Therapeutics.
  - Preclinical data concluded CA-4948 is synergistic with small molecule BTKi therapies that target BCR signaling and suggest the combination can overcome or reduce secondary resistance to BTKi therapies in marginal zone lymphoma.
    CA-4948 is able to cross the blood-brain barrier in a preclinical murine model of CNS lymphoma, producing significant and dose-dependent anti-tumor activity and survival advantage.
- Curis expects to have 10-20 patients in AML/MDS patients with SF3B1 or U2AF1 spliceosome mutation enrolled by year-end 2021.
  - Curis plans to provide an update on efficacy and safety from these patients in January. Data may not be fully matured or complete at this time.
    Curis expects to present additional data from the 10-20 patients with spliceosome mutations in more detail in the first half of 2022. Data from these patients may provide for an opportunity to explore discussions with the FDA on a registrational path forward in the first half of 2022.

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

Enrollment remains on track in the ongoing Phase 1 dose escalation study of CI-8993, Curis's first-in-class monoclonal anti-VISTA antibody for the treatment of R/R solid tumors.

Curis expects to report initial safety data from this trial in January.

Curis will hold a poster presentation with new preclinical data on CI-8993 at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting being held from November 12-14, 2021.
Title: Preclinical evaluation of anti-VISTA antibody CI-8993 in a syngeneic huVISTA-KI model
Presenting Author: Andrew M. Scott, MD Olivia Newton-John Cancer Research Institute, Tumour Targeting Laboratory, Melbourne, VIC, Australia
Abstract Number: 324
Abstracts were made available Tuesday, November 9, 2021, at 8:00 a.m.
Virtual ePoster presentations will be available Friday, November 12, 2021, at 7:00 a.m.

Upcoming Planned Milestones for 2022

In January, provide a clinical data update on our ongoing studies, including initial safety data from the ongoing Phase 1 monotherapy study of CI-8993 for the treatment of R/R solid tumors and the latest safety and efficacy data from the Phase 1/2 monotherapy study of CA-4948 in AML/MDS patients with spliceosome mutations that result in aberrant splicing of oncogenic IRAK4-L and patients with FLT3 mutations.
In the first half of the year, provide additional data from the ongoing Phase 1/2 monotherapy study of CA-4948 in patients with R/R AML/MDS at a medical meeting.
In the first half of the year, report initial data at a medical meeting from the ongoing Phase 1/2 combination study of CA-4948 plus ibrutinib in patients with B cell cancers.

Third Quarter 2021 Financial Results

For the third quarter of 2021, Curis reported a net loss of $11.1 million or $0.12 per share on both a basic and diluted basis, as compared to a net loss of $6.0 million, or $0.11 per share on both a basic and diluted basis for the same period in 2020. Curis reported a net loss of $31.8 million or $0.35 per share on both a basic and diluted basis, for the nine months ended September 30, 2021, as compared to a net loss of $22.4 million, or $0.52 per share on both a basic and diluted basis, for the same period in 2020.

Revenues for the third quarter of 2021 and 2020 were $3.0 million and $2.7 million, respectively. Revenues for the nine months ended September 30, 2021 were $7.5 million, as compared to $7.8 million for the same period in 2020. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses for the third quarter of 2021 were $13.1 million, as compared to $7.5 million for the same period in 2020. Operating expenses for the nine months ended September 30, 2021 were $37.0 million, as compared to $26.4 million for the same period in 2020, 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 $0.2 million for the third quarter of 2021, as compared to $0.1 million for the same period in 2020. Cost of royalty revenues for the nine months ended September 30, 2021 were $0.4 million, as compared to $0.4 million for the same period in 2020.

Research and Development Expenses. Research and development expenses were $8.6 million for the third quarter of 2021 as compared to $4.7 million for the same period in 2020. The increase in direct research and development expenses for the quarter is primarily attributable to increased clinical and manufacturing costs for our programs. Additionally, employee related costs increased by $2.3 million, primarily attributable to increased stock compensation and personnel costs as a result of additional headcount. Research and development expenses were $24.1 million for the nine months ended September 30, 2021 as compared to $17.5 million for the same period in 2020.

General and Administrative Expenses. General and administrative expenses were $4.3 million for the third quarter of 2021, as compared to $2.6 million for the same period in 2020. The increase in general administrative expense was driven primarily by higher costs for stock-based compensation, personnel, and professional and consulting services. General and administrative expenses were $12.5 million for the nine months ended September 30, 2021, as compared to $8.6 million for the same period in 2020.

Other Expense, Net. For the third quarter of 2021 and 2020, net other expense was $1.0 million and $1.3 million, respectively. Net other expense primarily consisted of imputed interest expense related to future royalty payments. Net other expense was $2.3 million for the nine months ended September 30, 2021, as compared to $3.8 million for the same period in 2020.

As of September 30, 2021, Curis's cash, cash equivalents and investments totaled $149.8 million, and there were approximately 91.6 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, November 9, 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 1/2 trial in patients with non-Hodgkin's lymphoma both as a monotherapy and in combination with BTK inhibitor ibrutinib. Curis is also evaluating CA-4948 in a Phase 1/2 trial in patients with acute myeloid leukemia and myelodysplastic syndromes, for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration. 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 1 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's 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, any statements with respect to Curis's plans, strategies, objectives or financial results; statements concerning product research, development, clinical trials and studies and commercialization plans, timelines, anticipated results or the therapeutic potential of drug candidates including any statements regarding the initiation, progression, expansion, use, efficacy, dosage and potential benefits of CA-4948 in clinical trials as a monotherapy and/or as a combination therapy, the progression, use and potential benefits of CI-8993, Curis's plans and timelines to provide preliminary, interim and/or additional data from its ongoing or planned clinical trials, and statements with respect to mutations or potential biomarkers; and statements of assumptions underlying any of the foregoing. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "predicts," "projects," "targets," "will," "may," "would," "could," "should," "continue," "potential," "focus," "strategy," "mission," 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, or the CRADA with NCI, 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 and its collaborators face the risk of 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 captions "Risk Factor Summary" and "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 September 30,		***Nine Months Ended September 30,***	
	2021	***2020***	***2021***	***2020***
Revenues, net:				
Royalties	$ 3,058	$ 2,720	$ 7,593	$ 7,681
Other revenue	—	—	1	211
Contra revenue	(19)	22	(80)	(81)
Total revenues, net	3,039	2,742	7,514	7,811
Operating expenses:				
Cost of royalties	151	135	376	382
Research and development	8,602	4,705	24,112	17,459
General and administrative	4,334	2,613	12,524	8,593
Total costs and expenses	13,087	7,453	37,012	26,434
Loss from operations	(10,048)	(4,711)	(29,498)	(18,623)
Other expense:				
Interest income	54	3	158	58
Imputed interest expense related to the sale of future royalty payments	(1,057)	(1,266)	(3,366)	(3,848)
Other income (expense), net	—	—	890	22
Total other expense	(1,003)	(1,263)	(2,318)	(3,768)
Net loss	(11,051)	(5,974)	(31,816)	(22,391)
Basic and diluted net loss per common share	$ (0.12)	$ (0.11)	$ (0.35)	$ (0.52)
Basic and diluted weighted average common shares outstanding	91,601,362	54,554,129	91,552,433	42,884,201

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands)

	September 30, 2021	***December 31, 2020***
ASSETS		
Cash, cash equivalents and investments	$ 149,826	$ 183,058
Restricted cash	726	816
Accounts receivable	2,959	3,043
Property and equipment, net	543	663
Operating lease right-of-use asset	5,962	6,578
Goodwill	8,982	8,982
Prepaid expenses and other assets	3,088	1,218
Total assets	$ 172,086	$ 204,358
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 8,816	$ 7,791
Operating lease liability	5,194	6,771

Debt obligations	7	891
Liability related to the sale of future royalties, net	55,167	58,235
Total liabilities	69,177	73,688
Total stockholders' equity	102,909	130,670
Total liabilities and stockholders' equity	$ 172,086	$ 204,358

SOURCE Curis, Inc.

For further information: For further information: Elif McDonald, VP, Investor Relations and Corporate Communications, Curis, Inc., 617-503-6583, emcdonald@curis.com

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