Curis Reports Second Quarter 2021 Financial Results

- Presented positive updated data from Phase 1/2 study of CA-4948 monotherapy in acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) at the European Hematology Association 2021 Virtual Congress (EHA) -
- Clear anticancer activity observed in molecularly-enriched AML/MDS population with spliceosome or FLT3 mutations; 4 of 4 evaluable patients (100%) achieved objective response -
- Further anticancer activity also observed in a broader population of AML/MDS patients; 9 of 11 evaluable patients (82%) achieved marrow blast reductions or maintenance of blast level for patients in the normal range at baseline -
- Additional clinical data expected by year-end in AML/MDS patients with SF3B1 and U2AF1 spliceosome mutations -
- Management to host conference call today at 4:30 p.m. ET -

LEXINGTON, Mass., Aug. 3, 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 second quarter ended June 30, 2021.

"In the second quarter of 2021, we continued executing on planned milestones across our pipeline of next generation targeted cancer therapies designed to meaningfully improve and extend patients' lives. We drove important progress with our first-in-class, small molecule IRAK4 inhibitor CA-4948, expanding our clinical trials into nine distinct patient populations across AML/MDS and B cell cancers. In June, we presented updated data from our Phase 1/2 relapsed/refractory (R/R) AML/MDS study at EHA, which showcased continued improvements in clinical activity and robust tolerability in extremely fragile patients," said James Dentzer, President and Chief Executive Officer of Curis. "At the 300mg BID dose we are seeing clear anticancer activity and are achieving pharmacokinetic (PK) exposure in patients that correlates to 98% inhibition in preclinical models. In addition, we are encouraged by a predictable and manageable safety profile with no dose-limiting toxicities related to myelosuppression and no overlapping dose-limiting toxicities with existing anticancer therapies planned for dosing in combination with CA-4948. The data at EHA also highlighted that we have identified a subset of patients with specific mutations that may make their disease highly amenable to CA-4948 monotherapy; all 4 of 4 evaluable patients with spliceosome or FLT3 mutations experienced an objective response. With further expansion of this group of patients, we may be able to identify a rapid path to regulatory approval for CA-4948. We also reported that even in patients without these specific mutations, CA-4948 demonstrated consistent tumor burden reduction, providing opportunities for combination development in a broader population. We expect to begin enrolling patients later this year in combination therapy evaluating CA-4948 with azacitidine or venetoclax. In total, we are exploring CA-4948 in four distinct cohorts in AML/MDS in addition to lower risk MDS, which is the subject of a separate Investigator Sponsored Trial (the LUCAS IST). We are also exploring CA-4948 in combination with ibrutinib across four additional cohorts in B cell cancers."

Mr. Dentzer added, "Lastly, we are also pleased with the continuing dose escalation in our ongoing Phase 1 study of CI-8993, our first-in-class monoclonal anti-VISTA antibody for the treatment of patients with R/R solid tumors.

"We look forward to providing an update on enrollment progress for all studies, including data updates for the spliceosome cohort in AML/MDS and the VISTA study, later this year."

Second Quarter 2021 and Recent Operational Highlights

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

At EHA, Curis presented interim data from the ongoing Phase 1/2 study of CA-4948 monotherapy in patients with R/R AML/MDS. The data were as of April 30, 2021 (the cut-off date) and were consistent with previously announced findings, including:

- Objective responses observed in 4 of 4 (100%) evaluable patients in the enriched population of patients with a targeted mutation (spliceosome or FLT3 mutation); these enriched populations will be studied in monotherapy expansion cohorts
- Marrow blast reductions, or maintenance of blast level for patients in the normal range at baseline, in 9 of 11 (82%) patients without spliceosome or FLT3 mutations; this broader population will be studied in combination therapy in expansion
- Efficacy confirmed with positive safety findings:
  - Clear efficacy observed at 300mg twice daily dosing
  - MTD not exceeded until 500mg BID
  - No overlap in dose-limiting toxicities with azacitidine and venetoclax, which are planned for combination with CA-4948
  - No dose-limiting toxicities related to myelosuppression
  - Dose-limiting side effect at higher doses consists of uncomplicated rhabdomyolysis (elevated CPK and muscle soreness), which was manageable, quickly and easily detected, readily reversible, and did not limit further treatment at a reduced dose level

Of note, those patients who experienced rhabdomyolysis at higher doses generally had predisposing factors, such as concomitant administration of statins or strenuous exercise

Alongside the EHA data, Curis determined 300mg BID to be the recommended Phase 2 dose as it demonstrated clear anticancer activity, a manageable and predictable safety profile and PK exposure in patients that correlates to near complete target engagement in preclinical models (98%)
Also at EHA, Curis reported non-clinical data demonstrating synergistic antitumor activity of CA-4948 in combination with azacitidine and venetoclax in leukemia cells, providing supportive rationale for clinical studies evaluating of combination therapy for AML/MDS patients
The Phase 1/2 study of CA-4948 in AML/MDS was expanded to include both a monotherapy dose expansion and a combination dose escalation:

Monotherapy:

R/R MDS patients with/without spliceosome mutation
R/R AML patients with/without FLT3 mutation

Combination therapy:

CA-4948 + azacitidine, for patients naïve to HMA
CA-4948 + venetoclax, for patients naïve to venetoclax
The Phase 1/2 study of CA-4948 in B cell cancers was expanded to include a combination dose escalation and dose expansion across four patient cohorts

Combination therapy:

BTKi-naïve patients with marginal zone lymphoma
BTKi-naïve patients with primary CNS lymphoma
BTKi-naïve patients with ABC-DLBCL
Patients who have developed adaptive resistance to ibrutinib

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

Enrollment is continuing 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 later in 2021
In June 2021, Curis hosted a virtual symposium entitled: *VISTA: A New Immune Checkpoint in Cancer, Autoimmunity, and Beyond*, gathering thought-leaders in industry and academia to discuss emerging understanding and opportunities surrounding the immune checkpoint

Upcoming Planned Milestones

In the second half of 2021, initiate dosing in the combination stage of the Phase 1/2 study of CA-4948 plus azacitidine and CA-4948 plus venetoclax
By year-end 2021, report additional clinical 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
By year-end 2021, report initial safety data from the ongoing Phase 1 monotherapy study of CI-8993 for the treatment of R/R solid tumors
In the first half of 2022, 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

Second Quarter 2021 Financial Results

For the second quarter of 2021, Curis reported a net loss of $10.8 million or $0.12 per share on both a basic and diluted basis, as compared to a net loss of $6.7 million, or $0.17 per share on both a basic and diluted basis for the same period in 2020. Curis reported a net loss of $20.8 million, or $0.23 per share on both a basic and diluted basis, for the six months ended June 30, 2021, as compared to a net loss of $16.4 million, or $0.44 per share on both a basic and diluted basis, for the same period in 2020.

Revenues for the second quarter of 2021 and 2020 were $2.3 million and $2.4 million, respectively. Revenues for the six months ended June 30, 2021 were $4.5 million, as compared to $5.1 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 second quarter of 2021 were $12.9 million, as compared to $7.8 million for the same period in 2020. Operating expenses for the six months ended June 30, 2021 were $23.9 million, as compared to $19.0 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 $0.1 million for the second quarter of 2021, as compared to $0.1 million for the same period in 2020. Cost of royalty revenues for the six months ended June 30, 2021 were $0.2 million, as compared to $0.2 million for the same period in 2020.

Research and Development Expenses. Research and development expenses were $8.8 million for the second quarter of 2021 as compared to $5.3 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 $1.4 million, primarily attributable to increased stock compensation and personnel costs as a result of additional headcount. Research and development expenses were $15.5 million for the six months ended June 30, 2021 as compared to $12.8 million for the same period in 2020.

General and Administrative Expenses. General and administrative expenses were $4.1 million for the first second quarter of 2021, as compared to $2.4 million for the same period in 2020. The increase in general administrative expense was driven primarily by higher costs for stock-based compensation, personnel, professional and consulting services, and legal services. General and administrative expenses were $8.2 million for the six months ended June 30, 2021, as compared to $6.0 million for the same period in 2020.

Other Expense, Net. For the second quarter of 2021 and 2020, net other expense was $0.2 million and $1.3 million, respectively. Net other expense primarily consisted of imputed interest expense related to future royalty payments, partially offset in the second quarter of 2021 by a gain of $0.9 million related to extinguishment of debt. Net other expense was $1.3 million for the six months ended June 30, 2021, as compared to $2.5 million for the same period in 2020.

As of June 30, 2021, Curis's cash, cash equivalents and investments totaled $160.7 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, August 3, 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 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 LUCAS IST, 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 June 30,		***Six Months Ended June 30,***	
	2021	***2020***	***2021***	***2020***
Revenues, net:				
Royalties	$ 2,348	$ 2,446	$ 4,535	$ 4,961
Other revenue	1	—	1	211
Contra revenue	(63)	(86)	(61)	(104)
Total revenues, net	2,286	2,360	4,475	5,068
Operating expenses:				
Cost of royalties	116	122	225	247
Research and development	8,753	5,282	15,510	12,754
General and administrative	4,067	2,386	8,190	5,980
Total costs and expenses	12,936	7,790	23,925	18,981
Loss from operations	(10,650)	(5,430)	(19,450)	(13,913)
Other expense:				
Interest income	58	5	104	55

Imputed interest expense related to the sale of future royalty payments	(1,136)	(1,284)	(2,309)	(2,581)
Other income (expense), net	890	1	890	22
Total other expense	(188)	(1,278)	(1,315)	(2,504)
Net loss	(10,838)	(6,708)	(20,765)	(16,417)
Basic and diluted net loss per common share	$ (0.12)	$ (0.17)	$ (0.23)	$ (0.44)
Basic and diluted weighted average common shares outstanding	91,547,390	39,517,045	91,527,563	36,985,117

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2021	***December 31, 2020***
ASSETS		
Cash, cash equivalents and investments	$ 160,682	$ 183,058
Restricted cash	816	816
Accounts receivable	2,379	3,043
Property and equipment, net	580	663
Operating lease right-of-use asset	6,171	6,578
Goodwill	8,982	8,982
Prepaid expenses and other assets	1,583	1,218
Total assets	$ 181,193	$ 204,358
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 7,234	$ 7,791
Operating lease liability	5,345	6,771
Debt obligations	—	891
Liability related to the sale of future royalties, net	56,140	58,235
Total liabilities	68,719	73,688
Total stockholders' equity	112,474	130,670
Total liabilities and stockholders' equity	$ 181,193	$ 204,358

SOURCE Curis, Inc.

For further information: Investor Relations, Stephanie Ascher, Stern Investor Relations, Inc., (212) 362-1200, Stephanie.Ascher@sternir.com

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