Curis Reports First Quarter 2021 Financial Results

- Abstract with encouraging clinical data from Phase 1/2 study of CA-4948 in acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) was released earlier today; additional clinical data to be presented in oral presentation at the European Hematology Association 2021 Virtual Congress (EHA) -
- Phase 1/2 study in AML and MDS expanded to include combinations of CA-4948 plus azacitidine and CA-4948 plus venetoclax -
- Phase 1/2 study in non-Hodgkin lymphoma (NHL) expanded to include combination of CA-4948 plus ibrutinib; dosing was initiated in Q1 -
- Management to host conference call today at 4:30 p.m. ET -

LEXINGTON, Mass., May 12, 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 first quarter ended March 31, 2021.

"The first quarter of 2021 saw continued momentum for our pipeline of next generation targeted cancer therapies designed to meaningfully improve and extend patients' lives. We continued to make important progress with CA-4948, our first-in-class, small molecule inhibitor of IRAK4, now in three clinical trials after expanding into one new study earlier this year with the Phase 2 LUCAS IST for patients with lower-risk MDS, as well as expanding our previous Phase 1/2 study in patients with relapsed/refractory (R/R) NHL to include the combination of CA-4948 plus ibrutinib. We were also very pleased to announce that CA-4948 was granted Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of AML and MDS, highlighting the unique potential of our IRAK4 program," said James Dentzer, President and Chief Executive Officer of Curis. "We are especially excited about the AML/MDS data published today in the EHA abstract, and we look forward to providing additional data from this study in the oral presentation at EHA next month."

Mr. Dentzer added, "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 and look forward to providing initial data from this study later this year."

First Quarter 2021 and Recent Operational Highlights

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

Today, EHA released the Curis abstract reporting interim data from the ongoing Phase 1/2 study of CA-4948 in patients with R/R AML and MDS. The data are from 15 patients as of February 8, 2021 (the cut-off date) and are consistent with previously announced findings, including marrow blast reductions observed at all tested doses in 8 of 9 (89%) evaluable patients with elevated blast counts at baseline, with 1 patient experiencing a full hematologic recovery complete response, 1 complete remission with incomplete hematologic recovery (CRi) with negative minimal residual disease, and 2 bone marrow complete responses (CRs).

All 3 patients presenting with SF3B1 or U2AF1 spliceosome mutations achieved marrow CR or better
All patients with objective responses also saw signs of hematologic recovery
Updated safety, pharmacodynamic, and efficacy data, as well as data from additional trial participants, will be featured in an oral presentation at EHA on Friday, June 11 at 9:00 am CEST (3:00 am EDT).

Curis updated that the 500mg BID dosing regimen in the AML/MDS study has exceeded the maximum tolerated dose according to protocol guidelines. Two patients in the cohort were observed to have dose-limiting toxicities, one of whom had Grade 3 rhabdomyolysis and the other experienced Grade 3 syncope. Both AEs resolved after discontinuation of dosing. Current enrollment is exploring lower dose levels to determine the appropriate recommended phase 2 dose (RP2D).
Also today, Curis reported non-clinical data to be presented in a poster at EHA demonstrating synergistic antitumor activity of CA-4948 in combination with azacitidine and venetoclax in leukemia cells, providing supportive rationale for evaluation of the combinations in a clinical setting for AML and MDS patients.
The Phase 1/2 study of CA-4948 in AML and MDS was expanded to include both a combination dose escalation and a monotherapy dose expansion:

Combination dose escalation, which will start at 200mg BID, will include two cohorts:

1) CA-4948 + azacitidine, for patients with AML or MDS who are naïve to hypomethylating agents (HMA)

2) CA-4948 + venetoclax, for patients with AML or MDS after first line therapy who are naïve to venetoclax

Monotherapy dose expansion, which will begin after the RP2D is determined, will include four cohorts:

1) MDS patients, R/R to HMA, with spliceosome mutations
2) MDS patients, R/R to HMA, without spliceosome mutations
3) R/R AML patients with FLT3-ITD mutation
4) R/R AML patients with FLT3 WT

In April 2021, Curis announced that the U.S. Food and Drug Administration (FDA) had granted Orphan Drug designation for CA-4948 for the treatment of AML and for treatment of MDS.
Also in April, Curis presented updated data on a potentially predictive biomarker demonstrating target engagement in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2021.
In February, Curis announced the dosing of the first patient in its Phase 1/2 combination study of CA-4948 plus ibrutinib, for the treatment of patients with R/R NHL or other hematologic malignancies. In preclinical models, CA-4948 demonstrated synergistic anti-cancer activity when combined with a potent BTK inhibitor such as ibrutinib. Curis expects to report initial data from this study in the second half of 2021.
Earlier in February, Curis announced the initiation of the investigator-sponsored Phase 2 LUCAS study of CA-4948 for the treatment of anemia in patients with very low, low, or intermediate-risk MDS. The study is expected to start recruitment in the second quarter of 2021.

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

Curis continues to enroll patients in the ongoing Phase 1 dose escalation study of its first-in-class monoclonal anti-VISTA antibody for the treatment of R/R solid tumors and expects to report initial clinical data in the second half of 2021.

Upcoming 2021 Planned Milestones

Report additional clinical data at the EHA 2021 Virtual Congress from the Phase 1/2 monotherapy study of CA-4948 in patients with AML and MDS, including patients with spliceosome mutations that result in aberrant splicing of oncogenic IRAK4-L.
Initiate dosing in the Phase 1/2 combination study of CA-4948 plus azacitidine and CA-4948 plus venetoclax in patients with R/R AML and MDS.
In the second half of 2021, report initial data from the ongoing Phase 1/2 combination study of CA-4948 plus ibrutinib in patients with R/R NHL.
In the second half of 2021, report initial data from the ongoing Phase 1 monotherapy study of CI-8993 for the treatment of R/R solid tumors.

First Quarter 2021 Financial Results

For the first quarter of 2021, Curis reported a net loss of $9.9 million or $0.11 per share on both a basic and diluted basis, as compared to a net loss of $9.7 million, or $0.28 per share on both a basic and diluted basis for the same period in 2020.

Revenues for the first quarter of 2021 and 2020 were $2.2 million and $2.7 million, respectively.

Operating expenses for the first quarter of 2021 were $11.0 million, as compared to $11.2 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 first quarter of 2021 and 2020.

Research and Development Expenses. Research and development expenses were $6.8 million for the first quarter of 2021 as compared to $7.5 million for the same period in 2020. The decrease in direct research and development expenses for the quarter is primarily attributable to the upfront license fee expense from our option and license agreement with ImmuNext that occurred during the first quarter of 2020. These costs were partially offset by a $0.3 million increase in employee related costs.

General and Administrative Expenses. General and administrative expenses were $4.1 million for the first quarter of 2021, as compared to $3.6 million for the same period in 2020. The increase in general administrative expense was driven primarily by higher costs for stock-based compensation and professional and consulting services, partially offset by lower legal services costs during the three months ended March 31,

2021.

Other Expense, Net. For the first quarter of 2021 and 2020, net other expense was $1.1 million and $1.2 million, respectively. Net other expense primarily consisted of imputed interest expense related to future royalty payments.

As of March 31, 2021, Curis's cash, cash equivalents and investments totaled $168.4 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, May 12, 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 the 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' 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 and potential benefits of CA-4948 in clinical trials as a monotherapy and 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 clinical trials, and statements with respect to 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 March 31,	
	2021	***2020***
Revenues, net:		
Royalties	$ 2,187	$ 2,515
Other revenue	—	211
Contra revenue, net	2	(17)
Total revenues, net:	2,189	2,709
Operating expenses:		
Costs of royalties	109	125
Research and development	6,757	7,473
General and administrative	4,123	3,593
Total costs and expenses	10,989	11,191
Loss from operations	(8,800)	(8,482)
Interest income	46	50
Imputed interest expense related to the sale of future royalties	(1,173)	(1,298)
Other income (expense), net	—	21
Total other expense	(1,127)	(1,227)
Net loss	(9,927)	(9,709)
Basic and diluted net loss per common share	$ (0.11)	$ (0.28)
Basic and diluted weighted average common shares outstanding	91,507,518	34,453,189

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	March 31, 2021	***December 31, 2020***
ASSETS		
Cash, cash equivalents and investments	$ 168,350	$ 183,058
Restricted cash	816	816
Accounts receivable	2,183	3,043
Property and equipment, net	620	663
Operating lease right-of-use asset	6,376	6,578
Goodwill	8,982	8,982
Other assets	3,266	1,218
Total assets	$ 190,593	$ 204,358
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 5,491	$ 7,791
Operating lease liability	5,490	6,771
Debt obligations	891	891
Liability related to the sale of future royalties, net	56,806	58,235
Total liabilities	68,768	73,688
Total stockholders' equity	121,915	130,670
Total liabilities and stockholders' equity	$ 190,593	$ 204,358

SOURCE Curis, Inc.

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https://investors.curis.com/2021-05-12-Curis-Reports-First-Quarter-2021-Financial-Results