Curis Announces Publication of CUDC-907 Phase 1 Clinical Trial Data in Lancet Oncology

Latest analysis of data presented at the American Society of Hematology's annual meeting in December, 2015

CUDC-907 demonstrated objective responses, including complete responses, in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL)

LEXINGTON, Mass., April 04, 2016 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, today announced the publication of results from the dose escalation part of the Phase 1 clinical trial in the journal Lancet Oncology. The publication, titled "*Safety, tolerability, and preliminary activity of CUDC-907, a first-in-class, oral, dual inhibitor of HDAC and PI3K, in patients with relapsed or refractory lymphoma or multiple myeloma: an open-label, dose-escalation, phase 1 trial*" was authored by the clinical investigators of the first-in-man Phase 1 study as well as members of Curis' clinical and scientific teams. The publication is also accompanied by an independent commentary in the journal titled "*Dual inhibition of oncogenic targets for B-cell malignancies*" by Paul G. Richardson, M.D., R.J. Corman Professor of Medicine at the Jerome Lipper Multiple Myeloma Center at Dana Farber Cancer Institute.

"The data from the Phase 1 monotherapy trial for CUDC-907, especially in heavily pretreated patients with relapsed/ refractory DLBCL are very encouraging and we look forward to data emerging from the current Phase 2 trial in patients with MYC-altered DLBCL," said Dr. Anas Younes, M.D., Chief of the Lymphoma Service of the Memorial Sloan Kettering Cancer Center in New York City, the Principal Investigator of the Phase 1 trial and the publication's senior author.

Based on the clinical activity observed in patients with relapsed/ refractory-DLBCL, particularly those with cancers harboring MYC alterations, Curis has initiated a Phase 2 trial to evaluate CUDC-907 in patients with MYC-altered RR-DLBCL. Additional details of the Phase 2 trial can be found at www.clinicaltrials.gov (study identifier: NCT02674750)

About CUDC-907:

CUDC-907 is an oral, dual inhibitor of Class I and II HDAC, as well as Class I PI3K enzymes. Specifically, CUDC-907 is designed to inhibit HDACs 1, 2, 3, 6 and 10 and PI3K-alpha, delta and beta isoforms. CUDC-907 is being investigated in clinical studies in patients with lymphomas and advanced solid tumors. The development of CUDC-907 has been supported in part by The Leukemia & Lymphoma Society (LLS) under a funding agreement established in 2011 between Curis and LLS's Therapy Acceleration Program.

About Curis, Inc.
Curis is a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907, a dual HDAC and PI3K inhibitor that is being investigated in two clinical studies in patients with lymphomas and solid tumors. Curis is also engaged in a broad 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 the PD-1 pathway/ VISTA, including PD-L1/VISTA antagonist CA-170, as well as to molecules designed to inhibit IRAK4, including lead candidate CA-4948. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge® for the treatment of advanced basal cell carcinoma.

Cautionary Note Regarding Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation Curis' expectations regarding: its plans and timing for conducting ongoing and planned clinical studies with CUDC-907 in various indications, including its Phase 2 clinical trial of CUDC-907 in patients with relapsed/ refractory DLBCL with MYC alterations and the potential benefits of CUDC-907. Forward-looking statements used in this press release may contain the words "believes," "expects," "anticipates," "plans," "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 and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis' drug candidates may cause unexpected toxicities and/or fail to demonstrate sufficient safety and efficacy in clinical trials and may never achieve the requisite regulatory approval needed for commercialization. There can be no guarantee that Curis' collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will maintain the financial resources necessary to continue financing its portion of research, development and commercialization costs or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Genentech and Roche may experience delays or failures in the manufacture and commercialization of Erivedge, regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge, and competing drugs may be developed that are superior to Erivedge, any of which could adversely affect the amount of royalty revenue that Curis receives from sales of Erivedge. Curis also faces risks relating to its wholly-owned subsidiary's Erivedge royalty-collateralized loan transaction, including the risk that it may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy the debt obligation or may otherwise lose its rights to royalties and royalty-related payments as a result of a foreclosure of the loan. Curis may not obtain or maintain necessary patent protection for its programs and could become involved in expensive and time consuming patent litigation and interference proceedings. Curis faces substantial competition from other companies developing cancer therapeutics. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Unstable market and economic conditions may adversely affect Curis' financial conditions and its ability to access capital to fund the growth of its business.

Curis also faces other important risks relating to its business, operations, financial condition and future prospects that are discussed in its Annual Report on Form 10-K for the year ended December 31, 2015 and other filings that it periodically makes with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis' 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.

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