# Curis Announces Removal of FDA Partial Clinical Hold on CUDC-427

## Curis Expects to Reinitiate Enrollment in Single Agent Phase 1 Study of CUDC-427 in Patients With Solid Tumors or Lymphoma

LEXINGTON, Mass., March 31, 2014 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company developing novel, targeted drug candidates for the treatment of human cancers, today reported that the U.S. Food and Drug Administration (FDA) has notified the Company that its complete response submission to the November 2013 partial clinical hold on CUDC-427 has been reviewed and that the FDA has determined that it is safe to proceed under the IND. The FDA also indicated that detailed official correspondence regarding the determination will be released in the near future. Curis will provide additional details, if applicable, based upon further communications from the FDA as they become available.

"We have worked diligently with the FDA and anticipate re-opening the monotherapy Phase 1 study as soon as possible," said Ali Fattaey, Ph.D., President and Chief Operating Officer of Curis. "We continue to believe that CUDC-427 has significant potential as an anti-cancer agent and expect to proceed with CUDC-427's overall development plan, including our planned study to investigate CUDC-427 in combination with capecitabine in HER-2 negative advanced breast cancer patients."

In November 2013, CUDC-427's Phase 1 study in patients with solid tumors or lymphoma was placed on partial clinical hold following the death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under the partial clinical hold, no new patients were to be enrolled in the study until Curis provided the FDA with the requested data and analyses of all patients treated with CUDC-427, together with a protocol amendment found to be acceptable to the FDA.

**About CUDC-427**

CUDC-427 is an oral, small molecule Smac mimetic that is designed to promote cancer cell death by antagonizing inhibitor of apoptosis (IAP) proteins. IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival by inhibiting programmed cell death, also known as apoptosis, which is a normal process inherent in every cell. Using IAP proteins and other anti-apoptotic factors, cancer cells evade apoptosis in response to a variety of signals, including those provided by anti-cancer agents such as chemotherapy, or naturally occurring inflammatory and immune signals transmitted through members of tumor necrosis factor (TNF) family. IAP inhibitors such as CUDC-427 are designed to counteract the effects of IAP proteins, thus shifting the balance away from cancer cell survival and allowing apoptosis to proceed.

**About Curis, Inc**

Curis is an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers. Curis is seeking to further the development of its pipeline of proprietary targeted cancer drug candidates, including CUDC-907, a dual histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) inhibitor, and CUDC-427, a small molecule antagonist of IAP proteins. Curis is also engaged in a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge®, the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma. Curis-discovered HSP90 inhibitor, Debio 0932 is being studied in patients with advanced lung and kidney cancers by partner Debiopharm. For more information, visit Curis' website at www.curis.com.

**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 statements regarding Curis' expectations for the timing of conducting upcoming and additional clinical studies with CUDC-427 as well as the potential benefits and safety of this drug candidate. 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, the FDA could impose additional restrictions on clinical trials of CUDC-427 which could delay, make more costly or otherwise adversely impact Curis' future development plans for CUDC-427, including its plans to proceed with future studies as in the combination study with capecitabine in HER-2 negative advanced breast cancer patients. Curis and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis' drug candidates, including CUDC-427, are unproven and 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. Curis will require substantial additional capital to fund the research and development of its drug development programs, and such capital may be difficult to obtain. 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. Unstable market and economic conditions may adversely affect Curis' financial condition 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 2013 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.*

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