Curis Announces Dosing of First Patient in Phase 1 Trial of CUDC-907 in Patients With Advanced/ Relapsed Solid Tumors

Trial Expected to Enroll Patients With Hormone Receptor Positive Breast Cancer and Patients With Midline Carcinoma With NUT Rearrangement

LEXINGTON, Mass., Dec. 18, 2014 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers, today announced that the first patient has initiated treatment with CUDC-907 in a Phase 1 clinical trial in patients with advanced or relapsed solid tumors, including hormone receptor positive (HR+)/ HER2-negative breast cancer or midline carcinoma with certain NUT gene rearrangements. CUDC-907 is an oral, dual inhibitor of histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) enzymes that is currently under investigation in the first-in-human Phase 1 clinical study in patients with relapsed or refractory lymphomas and multiple myeloma.

"We look forward to investigating the therapeutic potential of CUDC-907, a molecule with the unique ability to inhibit both HDAC and PI3K enzymes, in patients with hormone receptor positive breast cancer," said Pamela Munster, M.D., Principal Investigator of the study and Professor, Department of Medicine (Hematology/Oncology) at the University of California, San Francisco's Helen Diller Family Comprehensive Cancer Center. "Scientifically, CUDC-907 merits evaluation in patients with HR+ breast cancer in combination with hormonal therapy as HDACs are critical components of the estrogen receptor transcriptional complex. Additionally, the high prevalence of alterations in the PI3K pathway further supports the rationale of testing the molecule in this specific subset of patients with breast cancer."

"We are excited to initiate this study with CUDC-907 in patients with HR+ breast cancer and in patients with NUT midline carcinoma or NMC, a rare, aggressive cancer, genetically defined by rearrangements of the NUT gene," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "There are currently no therapies for patients with NMC. However, Curis' preclinical data and other published results in the field have demonstrated that NMCs may be sensitive to treatment with molecules that inhibit HDAC enzymes such as CUDC-907. Based on these data, we are eager to further investigate the potential of CUDC-907 in the treatment of patients with NMC."

About the Upcoming Solid Tumor Phase 1 Study

The solid tumor study is an open label, multi-center study to assess the safety, tolerability and pharmacokinetics of CUDC-907 in subjects with advanced, relapsed solid tumors, including hormone receptor positive breast cancer or midline carcinoma with NUT rearrangement. In the case of breast cancer, tumors must be estrogen receptor (ER+) and/or progesterone receptor (PR+) positive and HER2-negative, with disease progression following treatment with at least one prior hormonal therapy for advanced/metastatic disease or disease relapse while on adjuvant hormonal therapy. Additionally, ongoing treatment with tamoxifen, anastrozole, exemestane or letrozole is allowed.

The primary objective of this study is to determine the safety and tolerability of oral CUDC-907 using the recommended schedules of administration that have already been identified in the first-in-human trial of CUDC-907, namely 5 days "on"/2 days "off" weekly or three times a week in 21 day cycles. The secondary objectives of this study are to assess the plasma and tissue pharmacokinetics, to establish the maximum tolerated dose, the recommended Phase 2 dose in patients with solid tumor malignancies, to evaluate biomarkers of activity and the preliminary anti-cancer activity of CUDC-907.

For additional details regarding the study, please refer to www.clinicaltrials.gov (Identifier: NCT02307240)

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 currently undergoing investigation in a first-in-human trial to assess its safety, pharmacokinetics and preliminary anti-cancer activity in patients with relapsed/refractory lymphomas and multiple myeloma. The development of CUDC-907 is in part supported by The Leukemia & Lymphoma Society (LLS) under a funding agreement established in 2011 between Curis and LLS's Therapy Acceleration Program. For additional details of CUDC-907's Phase 1 studies, please refer to www.clinicaltrials.gov (study identifiers: NCT01742988 and NCT02307240).

About Curis, Inc.

Curis is an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers. Curis' pipeline of drug candidates includes CUDC-907, a dual HDAC and PI3K inhibitor, CUDC-427, a small molecule antagonist of IAP proteins and Debio 0932, an oral HSP90 inhibitor. 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. 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 Curis' expectations regarding: its plans and timing for conducting ongoing and planned clinical studies with CUDC-907 in various indications; the potential benefits of CUDC-907; and its expectations regarding further funding of the CUDC-907 development program by LLS. 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. Curis will require substantial additional capital to fund the research and development of its drug development programs. Curis 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. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 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.

CONTACT: For More Information:

Mani Mohindru, Ph.D.

Vice President, Corporate Strategy and Investor Relations

Curis, Inc.

617-503-6605

mmohindru@curis.com

Michael P. Gray

Chief Financial and Chief Business Officer

Curis, Inc.

617-503-6632

mgray@curis.com
