Curis Announces Investigational New Drug Application Filing by Roche to Initiate a Phase 2 Study of Erivedge(R) (vismodegib) in Idiopathic Pulmonary Fibrosis

Filing Triggers $3 Million Milestone Payment to Curis

LEXINGTON, Mass., June 23, 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 Roche has filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to initiate a multicenter, Phase 2 clinical study of Erivedge® (vismodegib) in patients with idiopathic pulmonary fibrosis (IPF), a chronic, debilitating lung disease. Roche and Genentech, a member of the Roche Group, develop and commercialize Erivedge under a collaboration agreement with Curis.

"We are pleased with this important decision by Roche to expand the development of Erivedge outside of oncology for the first time, especially in IPF where Hedgehog pathway activation is associated with the disease," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "IPF represents a serious unmet medical need and patients suffering from this disease are in need of improved treatment options. The IND filing is currently under review by the FDA and we look forward to providing additional details on the study as they become available."

While the underlying cause of IPF is not well understood, aberrant activation of the Hedgehog signaling pathway has been reported to play a role in the disease. Many developmental pathways, including the Hedgehog signaling pathway, play an essential role during human embryonic development but are generally inactivated later in life. Aberrant activation of these pathways is believed in many cases to lead to pathological events resulting in human disease such as cancer and IPF.

About the Phase 2 IPF Trial

Roche submitted the IND for a Phase 2 randomized, multi-center, double-blind, placebo-controlled, parallel-group study to evaluate the safety and efficacy of Erivedge in patients with IPF. Erivedge will be administered orally at a dose of 150 mg daily and the duration of treatment will be 52 weeks. The primary endpoint of the study is mean change in forced vital capacity (FVC) percent predicted from baseline to week 52 in patients with IPF. FVC is a measure of pulmonary function in patients with IPF. The secondary endpoints include change in diffusion capacity of the lung for carbon dioxide (DLCO), annualized rate of change in FVC, progression-free survival, time from randomization to first event of acute IPF exacerbation, change in quality of life measurements and safety. According to Roche, following FDA review of the IND, the study is anticipated to start enrollment later this year and is expected to enroll approximately 130 patients. For additional information about the study, please refer to www.clinicaltrials.gov (study identifier: NCT02168530).

About Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is a chronic, debilitating lung disease with unknown cause that occurs in adults and has very poor prognosis. The disease is characterized by thickening or scarring of lung tissue (fibrosis) over time, resulting in decreased oxygen supply to the brain and other organs. Currently, there is no cure for IPF and life expectancy for most people is approximately 3 to 5 years after diagnosis. Respiratory failure is the most common cause of death due to IPF. The prevalence of IPF is approximately 1 per 5,000 in men and 1 per 7,700 in women. In the United States, the National Heart, Lung and Blood Institute estimates an incidence of approximately 10 to 40 per 10,000 adults.

About Erivedge

Erivedge is designed to selectively target the Hedgehog signaling pathway, which is implicated in the development of certain types of cancer, including basal cell carcinoma (BCC).

Roche has developed Erivedge under a collaboration agreement with Curis. Erivedge was discovered by Genentech and jointly validated by Genentech and Curis through a series of preclinical studies. Through this collaboration, Genentech (U.S.), Roche (ex-U.S. excluding Japan) and Chugai Pharmaceuticals (Japan) are responsible for the clinical development and commercialization of Erivedge. Curis is eligible to receive cash payments assuming the successful achievement of specified clinical development and regulatory approval milestones, as well as royalties upon commercialization of Erivedge.

In January 2012, Erivedge became the first licensed medicine for patients with advanced BCC when the U.S. Food and Drug Administration (FDA) approved it following a priority review. Erivedge has since also been approved in multiple other territories worldwide, including Australia, Canada, Ecuador, European Union, Norway, Israel, Mexico, South Korea, Switzerland and Uruguay.

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 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 partner Debiopharm is studying HSP90 inhibitor Debio 0932 in patients with advanced lung cancer. 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 the potential benefits of treating IPF patients with Erivedge, and clinical development plans and timelines for the Phase 2 trial of Erivedge in IPF. 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 preclinical and clinical drug development programs. Curis and its collaborators' 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 and its collaborators may not achieve projected research, development and commercialization goals in the time frames that they publicly announce. Curis will require substantial additional capital to fund the research and development of its drug development programs. 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 and its collaborators face substantial competition. Curis is dependent upon its key collaborators and these collaborations may not be scientifically or commercially successful. Unstable market and economic conditions and other factors may adversely affect Curis' financial condition and its ability to access capital to fund the growth of its business. Curis could lose its rights to Erivedge royalties and related royalty payments if its wholly-owned subsidiary defaults under its secured credit agreement with BioPharma-II. Curis' stock price may not appreciate in value. 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 March 31, 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 forward-looking statements after the date of this press release except as may be required by law.

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