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Curis, Inc. Announces Dosing of First Patient in Hedgehog Antagonist Phase I Clinical Trial

Trial tests safety of systemic administration of a Hedgehog

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 31, 2007--Curis, Inc. (NASDAQ: CRIS), a therapeutic drug development company focusing on cancer, neurological and dermatological disease indications, announced today that Genentech, a collaborator, has treated the first patient in a Phase I clinical trial of a systemically administered small molecule Hedgehog antagonist for testing in advanced cancer.

The Phase I trial is designed as an open-label study of a systemic Hedgehog antagonist in patients with locally advanced or metastatic cancers that are refractory to standard therapy or for whom no standard therapies exist. The primary objectives of the Phase I trial are to evaluate the safety and tolerability of escalating doses of the Phase I molecule and to establish the maximum tolerated dose and dose limiting toxicities. The trial is expected to enroll approximately 50 patients spread across several dose-escalating cohorts. The successful completion of the Phase I trial will be dependent upon, among other things, the patient enrollment rate as well as the number of patients that will ultimately need to be treated to achieve the Phase I trial objectives.

"We are proud that this drug candidate has achieved this important milestone in what we believe is the first systemically administered Hedgehog antagonist tested in a clinical setting," said Curis President and CEO Dan Passeri. "Cancer remains a major unmet medical need. It is the second leading cause of death in the United States, with an estimated 1.4 million new cases of cancer per year and an estimated 565,000 deaths. Published reports cite the Hedgehog pathway as potentially implicated in various cancers, including breast, colorectal, esophageal, pancreatic, prostate and small cell lung cancers, among others. While we realize that we are in only the first phase of human clinical testing, we are hopeful that our Hedgehog antagonist technologies may one day provide a therapeutic benefit to cancer patients."

In October 2006, Genentech filed an Investigational New Drug (IND) application with the Food and Drug Administration (FDA) to initiate Phase I clinical testing of this small molecule drug candidate. Under the terms of the parties' June 2003 collaboration agreement, Genentech previously paid Curis a $3 million cash payment after filing the IND application for the drug candidate. Should this drug candidate successfully continue its development into subsequent stages of clinical testing and regulatory approval, Curis would be eligible to receive additional cash payments. In addition, in the event the drug candidate is successfully commercialized, Curis would be eligible to receive royalties on product sales.

About the Genentech Curis Collaboration

In June 2003, Curis and Genentech entered into a collaboration for the development of Hedgehog pathway inhibitors, also known as antagonists, with a current focus on the clinical testing of these drug candidates in a variety of cancer types. Numerous preclinical reports have linked abnormal activation of the Hedgehog pathway to the growth of several cancers.

About Curis, Inc.

Curis is a drug discovery and development company that is committed to leveraging its innovative signaling pathway drug technologies to create new medicines for cancer. In expanding its drug development efforts in the field of cancer, the Company is building upon its previous experiences in targeting signaling pathways in the areas of cancer, neurological disease, hair growth regulation and cardiovascular disease.

The Company's most advanced program is its Hedgehog antagonist program that is under collaboration with Genentech. As indicated above, Genentech is currently conducting a 50-patient Phase I clinical trial to test a systemically administered Hedgehog antagonist to regulate the Hedgehog pathway in cancers.

In 2006, the Company adjusted its business strategy to accelerate proprietary drug discovery and development activities. The Company initiated a novel cancer drug development platform (Targeted Cancer Drug Development Platform) that is focused upon designing multiple classes of compounds that consist of dual pharmacophores (active drug components) that are covalently bonded to one another to form single small molecule drug candidates. The two pharmacophores in each compound are being selected for potential therapeutic synergy against various cancers and are generally designed to target clinically validated cancer targets. The platform has been used to launch a number of multi-target inhibition cancer programs, each of

which represents a class of small molecule dual pharmacophore drug candidates that are focused on a specific profile of multi-target inhibition of validated cancer targets.

In addition to drug programs under development with the Company's Targeted Cancer Drug Development Platform, the Company has used its signaling pathway expertise to produce several preclinical product candidates. This technology and approach have been used in the fields of cancer (under two collaborations with Genentech), neurological disorders (under collaboration with Wyeth), hair growth (under collaboration with Procter & Gamble), kidney and other diseases (licensed to Ortho Biotech Products and under development at Centocor, both subsidiaries of Johnson & Johnson), as well as cardiovascular disease.

Cautionary Statement: This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements concerning Curis' expectations regarding the potential achievement of future clinical development objectives in its Hedgehog pathway inhibitor program under development with Genentech and the expected therapeutic benefits of the Company's Hedgehog antagonist technologies. Forward-looking statements used in this press release may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates" or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other factors that may cause the Company's actual results to be materially different from those indicated by such forward-looking statements including, among other things:

-- adverse results, delays and/or failures in the Company's and its strategic collaborators' and licensees' product development programs, including without limitation adverse events, difficulties with patient enrollment and other unplanned delays in its Hedgehog pathway inhibitor program currently under phase I clinical development with Genentech;

-- difficulties or delays in obtaining or maintaining required regulatory approvals for products being developed by the Company and its collaborators and licensees;

-- the Company's ability to obtain or maintain the patent and other proprietary intellectual property protection necessary for the development and commercialization of products based on its technologies;

-- changes in or the Company's inability to execute its business plan;

-- the risk that Curis does not obtain the additional funding required to conduct research and development of its product candidates and execute the Company's business plan;

-- unplanned cash requirements and expenditures;

-- risks relating to the Company's ability to enter into and maintain important strategic collaborations, including its ability to maintain its current collaboration agreements with Genentech, Wyeth, and Procter & Gamble as well as its license agreement with Ortho Biotech Products;

-- the risk that competitors will discover and develop signaling pathway-based or other competing therapeutics faster and more successfully than the Company and its collaborators are able to;

-- and other risk factors identified in the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent reports periodically filed with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company 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.

CONTACT: Curis, Inc.
Michael P. Gray, 617-503-6632
Chief Financial Officer
mgray@curis.com
or
For Curis, Inc.
Jenny Viscarolasaga, 617-503-6658
jenny@tworoadscommunications.com

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