Curis Announces Orphan Drug Designation for CUDC-907 in Diffuse Large B-Cell Lymphoma

LEXINGTON, Mass., April 6, 2015 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to its lead proprietary drug candidate, CUDC-907 for the treatment of Diffuse Large B-Cell Lymphoma (DLBCL).

"We are pleased to receive Orphan Drug Designation for CUDC-907 in DLBCL, which represents an area of significant unmet need, especially in the relapsed/ refractory setting," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "We are continuing to treat DLBCL patients with CUDC-907 in the expansion stage of our Phase 1 study and anticipate initiating a Phase 2 trial in this indication in the second half of the year."

CUDC-907 is an oral, dual inhibitor of histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) enzymes that is currently under investigation in Phase 1 clinical studies in patients with relapsed or refractory lymphomas or multiple myeloma as well as in patients with advanced/ relapsed solid tumors, including hormone receptor positive (HR+)/ HER2-negative breast cancer or midline carcinoma with certain NUT gene rearrangements.

The FDA's Orphan Drug Designation program grants orphan status to drugs and biologics that are intended for use in rare diseases/ or disorders, defined as those that affect fewer than 200,000 people in the U.S. or that affect more than 200,000 people in the U.S. where there is no reasonable expectation that the cost of developing and making the drug or biological product for the specific disease or condition will be recovered from sales in the U.S. Orphan drug designation may qualify the sponsor for financial incentives such as tax credits for qualified trials, the ability to apply for annual grant funding, clinical trial research design assistance and waiver of application fees associated with the approval of new drug under the Prescription Drug User Fee Act. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug or biological product for the same indication for a period of 7 years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or if the product with orphan exclusivity experiences a shortage. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

About Diffuse Large B-cell Lymphoma (DLBCL)

Non-Hodgkin lymphoma (NHL) is a clinically and pathologically heterogeneous group of lymphoproliferative malignancies that are predominantly of B-cell origin and have diverse patterns of behavior and responses to treatment. DLBCL is an aggressive form and the largest subtype of NHL, accounting for approximately 30% to 35% of all NHL diagnoses[1,2]. The American Cancer Society estimates that in 2015 there will be 71,850 new cases of NHL in the United States and 19,790 people will die of this disease[3]. In Europe, the estimated numbers of new cases of NHL and number of deaths due to the disease in 2012 was 93,400 and 37,900, respectively[4].

References:

[1]Crit Rev Oncol Hematol. 2013 Aug;87(2):146-71.

[2]Non-Hodgkin's Lymphoma Classification Project, 1997

[3]CA Cancer J Clin 2015;65:5-29

[4]European Journal of Cancer 49 (2013) 1374-1403

About Curis, Inc.

Curis is a biotechnology company focused on the development and commercialization of innovative 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 CUDC-305, an oral HSP90 inhibitor. Curis is also engaged in a broad collaboration with Aurigene in the areas of immuno-oncology and precision oncology. Curis is also party to a collaboration agreement 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 the potential benefits of having received orphan drug designation for 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, 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.

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