Curis Expands Cancer Drug Pipeline With Small Molecule PD-L1/ VISTA Immune Checkpoint Antagonist and IRAK4 Kinase Inhibitors

Company exercises options under Aurigene collaboration to license orally available small molecules for immuno-oncology and precision oncology

Curis selects program of small molecules targeting PD-L1/ TIM-3 as the second immuno-oncology program under the Aurigene collaboration

LEXINGTON, Mass., Oct. 19, 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, today announced the expansion of its pipeline with the addition of two programs, the first of which is an oral, small molecule immune checkpoint antagonist targeting programmed death ligand-1 (PD-L1) and V-domain Ig suppressor of T cell activation (VISTA), and the second is focused on inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4).

The additions to the pipeline come through the Company's exercise of its options under a collaboration agreement with Aurigene announced earlier this year. In the area of immuno-oncology, Curis exercised its option to exclusively license a first-in-class oral, small molecule antagonist designated as CA-170 that targets PD-L1 and VISTA, which function as negative checkpoint regulators of immune activation. CA-170 was selected from the broad PD-L1 antagonist program that the companies have been engaged in since the collaboration was established in January 2015.

Curis also exercised its option to exclusively license a program of orally available small molecule inhibitors of IRAK4 kinase. IRAK4 is a serine/ threonine kinase involved in the regulation of innate immune responses and also plays an important role in certain hematologic cancers. IRAK4 is inappropriately activated, and drives pro-survival and cytokine mediated pathways in cancers such as activated B cell-diffuse large B cell lymphoma (ABC-DLBCL), an aggressive form of lymphoma with poor prognosis. Targeting IRAK4 has potential therapeutic implications in both cancer and cytokine-driven inflammatory and autoimmune diseases.

The exercise of options for the PD-L1/VISTA and IRAK4 programs resulted in an aggregate one-time payment of $6 million by Curis to Aurigene in exchange for an exclusive, royalty-bearing license to develop, manufacture and commercialize compounds from the programs, including the development candidate, CA-170 and products containing such compounds, anywhere in the world with the exception of India and Russia, where Aurigene will hold an exclusive, royalty-free, fully paid license to commercialize such compounds.

Additionally, Curis has selected a second preclinical program within the immuno-oncology collaboration with Aurigene that is focused on evaluating small molecule antagonists with dual PD-L1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties. TIM-3 is an inhibitory checkpoint molecule that plays an important role in immune suppression and is co-expressed with programmed cell death-1 (PD-1) receptors on highly exhausted cytotoxic T cells in tumor tissues as well as expressed on certain regulatory T cells.

Curis expects that Aurigene scientists will present data from the PD-L1/VISTA immuno-oncology and the IRAK4 programs at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, which will take place Nov. 5-9 in Boston.

"We are pleased with the progress in our collaboration with Aurigene and the small molecule candidates emerging from the PD-L1 antagonist program," said Ali Fattaey, Ph.D., Curis' President and CEO. "Based on its preclinical profile in multiple *in vitro* and *in vivo* activity and safety models, we have selected CA-170 as our clinical candidate. By targeting both PD-L1 and VISTA with CA-170, we potentially have the opportunity to address exhausted T cells as well as other inhibitory immune cells such as myeloid derived suppressor cells or MDSCs, in the tumor microenvironment with one drug candidate. We believe that this property of targeting two unique checkpoint regulators provides CA-170 with the potential to not only address, but potentially expand beyond tumors with PD-L1 overexpression or those that may have relapsed after PD-1/ PD-L1 targeting therapies. Development of CA-170 is a priority for Curis, and we and Aurigene are working diligently to complete the required IND-enabling studies in the coming months. We expect to file an IND and initiate Phase 1 clinical testing of CA-170 during the first half of 2016. We also expect to file an IND for development of the IRAK4 inhibitor within the first half of 2016."

Dr. Fattaey continued, "We are also encouraged with the progress in our second immuno-oncology program that is generating small molecules targeting PD-L1 and TIM3, which may provide for additional opportunities to relieve the inhibitory effects of multiple immune checkpoints on exhausted T cells using our small molecule antagonist approach."

The development of the Company's immuno-oncology programs will be led by David Tuck, M.D., the Company's Vice President, Clinical and Translational Sciences. Dr. Tuck joined Curis from EMD Serono in May 2015, where he served as Senior Medical Director in the Oncology Translational Innovation program. Prior to that, Dr. Tuck was employed by Bristol-Myers Squibb Global Oncology Research in the role of Translational Physician for ipilimumab, with a primary focus on external development of immune checkpoint inhibitors in solid tumors and hematological malignancies. Dr. Tuck was previously an Associate Professor at Yale University and Associate Director of the Yale Cancer Center. Dr. Tuck earned his Medical Degree at the University of Vermont School of Medicine and is board certified in internal medicine, medical oncology and hematology.

Dr. Tuck said, "I am excited to lead the development of our immuno-oncology drug candidates and believe that oral, small molecule checkpoint inhibitors may provide a favorable drug profile to better address immune-related adverse events and the potential for combination with other therapies in a convenient manner for patients."

About Curis, Inc.

Curis is a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907, an oral dual HDAC and PI3K inhibitor that is being investigated in two clinical studies in patients with lymphomas and solid tumors. Curis is also engaged in a broad collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exercised options to exclusively license oral small molecule antagonists

of PD-L1/ VISTA and IRAK4. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge® 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 statements about: Curis' expectations regarding its plans to file two INDs in first half of 2016 for drug candidates under the collaboration with Aurigene; Curis' belief about the expected benefits of the collaboration for Curis; the potential therapeutic benefits of CA-170 and other programs that Curis may develop under the collaboration; Curis' ability to advance molecules from the collaboration into clinical development; and any other statements about Curis regarding clinical developments. Forward-looking statements used in this press release may also 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, there can be no guarantee that the collaboration agreement 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. Curis' expectations could also be affected by risks and uncertainties relating to a failure of Curis or Aurigene to fully perform under the collaboration agreement and/or any early termination of the collaboration agreement, adverse results of clinical trials and preclinical studies that are the subject of the collaboration, including subsequent analysis of existing data and new data received from ongoing and future studies, the content and timing of decisions made by the U.S. Food & Drug Administration and other regulatory authorities, investigational review boards at clinical trial sites, and publication review bodies, and Curis' ability to enroll patients in clinical trials that may be initiated under the collaboration. Furthermore, Curis or Aurigene may not obtain or maintain necessary patent protection for the programs that are the subject of the collaboration 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 and developments relating to Curis's business 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 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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