Curis Announces FDA Acceptance of Investigational New Drug Application for CA-170, the First Orally Available Small Molecule to Target and Inhibit Immune Checkpoints

LEXINGTON, Mass., June 01, 2016 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective therapeutics for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) application for CA-170. CA-170 is a first-in-class orally available small molecule that has been designed to target and inhibit the immune checkpoints, Programmed Death Ligand-1 (PD-L1) and V-domain Immunoglobulin Suppressor of T-cell Activation (VISTA).

"The acceptance of CA-170's IND by the FDA marks an important milestone in the advancement of immuno-oncology therapy," said Ali Fattaey, Ph.D., Curis's president and CEO. "The last few years have seen the successful development and commercial launch of multiple checkpoint inhibitors to treat a broad range of human cancers. However, all checkpoint inhibitors developed thus far have been monoclonal antibodies, with similar pharmacokinetic properties, and can only be administered by IV infusion. Today, the FDA has cleared us to test the first small molecule checkpoint inhibitor, CA-170, that will be taken orally by cancer patients. We envision that the pharmacokinetic properties of a small molecule will likely provide an advantage in dosing flexibility of a checkpoint inhibitor, either as a monotherapy or in combination with other cancer treatment regimens. We believe that, if successful, CA-170 can provide a compelling treatment alternative for patients and physicians."

CA-170 is an orally available, small molecule designed to selectively target and inhibit both PD-L1 and VISTA checkpoint regulators of immune activation. Preclinical data have demonstrated that CA-170 can induce effective proliferation and cytokine production by T cells in culture that are specifically suppressed by PD-L1 or VISTA. In addition, CA-170 demonstrated *in vivo* anti-tumor activity similar to anti-PD-1 or anti-VISTA antibodies in multiple mouse tumor models and appeared safe to administer based on toxicology studies.

About Curis, Inc.
Curis is a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907 that is being investigated in clinical studies in patients with lymphomas and solid tumors. Curis is engaged in a broad collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of the PD-1 and VISTA pathways, including PD-L1/VISTA antagonist CA-170, as well as to molecules designed to inhibit the IRAK4 kinase, including CA-4948. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are commercializing Erivedge® for the treatment of advanced basal cell carcinoma, and are further developing Erivedge in other diseases including idiopathic pulmonary fibrosis and myelofibrosis. 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 advantages and benefits of small molecule checkpoint inhibitors. Forward-looking statements 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 may experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Curis Royalty may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy its royalty-collateralized debt obligation or may otherwise lose its rights to Erivedge royalties and royalty-related payments as a result of a foreclosure of the loan. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Curis also faces risks relating to: potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies; competition; its ability to obtain or maintain necessary patent protection; unstable market and economic conditions; unplanned expenses; and 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 period ended March 31, 2016 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's 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.

For More Information:

James E. Dentzer
Chief Financial Officer & Chief Administrative Officer
Curis, Inc.
617-503-6597
jdentzer@curis.com

Media Contact:
David Schull
Russo Partners

212-845-4271
david.schull@russopartnersllc.com

---

https://investors.curis.com/Curis-Announces-FDA-Acceptance-of-Investigational-New-Drug-Application-for-CA-170-the-First-Orally-Available-Small-Molecule-to-Target-and-Inhibit-Immune-Checkpoints