October 19, 2015

Cerulean Announces First Patient Dosed in Clinical Trial to Evaluate Weekly Dosing Schedule with CRLX101

Company Expects Enrollment Completion H2 2016

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Cerulean Pharma Inc. (NASDAQ:CERU), a clinical stage company developing nanoparticle-drug conjugates (NDCs), today announced that the first patient has been dosed in a trial exploring a dose-intensive schedule for its lead NDC, CRLX101, in patients with advanced solid tumor malignancies. The trial will explore safety and tolerability of CRLX101 when administered in a weekly dosing regimen. This trial is expected to complete enrollment in the second half of 2016.

"I joined Cerulean because I believe that CRLX101 has the potential to be approved in multiple indications, and I am excited to lead that effort. CRLX101 has been studied in over 300 patients, and I am encouraged by the data generated to date with bi-weekly dosing in multiple tumor types when given as monotherapy and in combination with other therapies," said Adrian Senderowicz, M.D., Senior Vice President and Chief Medical Officer of Cerulean. "The tolerability we have seen with CRLX101 allows us to explore whether an increase in intensity with a weekly dosing regimen may enhance the therapeutic index, enabling additional registration strategies using this novel regimen."

This is an open-label, dose-escalation study in patients with advanced solid tumor malignancies with up to 18 patients receiving weekly CRLX101 alone, and up to 18 patients receiving weekly CRLX101 in combination with bi-weekly Avastin®. The trial is designed to determine the maximum tolerated dose for potential indications of CRLX101. Preliminary evidence of anti-tumor activity also will be evaluated.

About CRLX101

CRLX101 is a nanoparticle-drug conjugate (NDC) designed to concentrate in tumors and slowly release its anti-cancer payload, camptothecin, inside tumor cells. CRLX101 inhibits topoisomerase 1 (topo 1), which is involved in cellular replication, and also inhibits hypoxia-inducible factor-1α (HIF-1α), which research suggests is a master regulator of cancer cell survival mechanisms. CRLX101 has shown activity in four different tumor types, both as monotherapy and in combination with other cancer treatments. CRLX101 is in Phase 2 clinical development and has been dosed in more than 300 patients. The U.S. FDA has granted CRLX101 Orphan Drug designation for the treatment of ovarian cancer and Fast Track designation in combination with Avastin in metastatic renal cell carcinoma.

About CRLX301

CRLX301 is a dynamically tumor-targeted NDC designed to concentrate in tumors and slowly release its anti-cancer payload, docetaxel, inside tumor cells. In preclinical studies, CRLX301 delivers up to 10 times more docetaxel into tumors, compared to an equivalent milligram dose of commercially available docetaxel and was similar to or better than docetaxel in seven of seven animal models, with a statistically significant survival benefit seen in five of those seven models. In addition, preclinical data show that CRLX301 had lower toxicity than has been reported with docetaxel in similar preclinical studies. CRLX301 is currently in Phase 1/2a clinical development.

About Cerulean Pharma

The Cerulean team is committed to improving treatment for people living with cancer. We apply our Dynamic Tumor Targeting Platform to create a portfolio of NDCs designed to selectively attack tumor cells, reduce toxicity by sparing the body's normal cells, and enable therapeutic combinations. Our first platform-generated candidate, CRLX101, is in multiple clinical trials in combination with other cancer treatments, all of which aim to unlock the power of combination therapy. Our second platform-generated candidate, CRLX301, is in a Phase 1/2a clinical trial. For more information, please visit www.ceruleanrx.com.

About Cerulean's Dynamic Tumor Targeting™ Platform

Cerulean's Dynamic Tumor Targeting Platform creates NDCs that are designed to provide safer and more effective cancer treatments. We believe our NDCs concentrate their anti-cancer payloads inside tumors while sparing normal tissue because they are small enough to pass through the "leaky" vasculature present in tumors but are too large to pass through the wall of healthy blood vessels. Once inside tumors, our NDCs enter tumor cells where they slowly release anti-cancer payloads from within the tumor cells.

Cautionary Note on Forward Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about the clinical development of our product candidates, statements about our estimated research and development expenses and sufficiency of cash to fund specified use of cash and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation of clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals, availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" section of our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 6, 2015, and in other filings that we make with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligation to update any forward-looking statements included in this press release.

Avastin is a registered trademark of Genentech, Inc.

View source version on businesswire.com: http://www.businesswire.com/news/home/20151019005474/en/

Cerulean Pharma Inc.
Nicole P. Jones, 617-551-9606
Director, Investor Relations and
Corporate Communications
njones@ceruleanrx.com

Source: Cerulean Pharma Inc.