October 6, 2016

Cerulean Announces Data Presentations at the 2016 European Society for Medical Oncology Annual Meeting

WALTHAM, Mass.--(BUSINESS WIRE)-- Cerulean Pharma Inc. (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today announced it will present clinical data from its CRLX101 and CRLX301 programs at the 2016 European Society for Medical Oncology (ESMO) Annual Meeting being held in Copenhagen, Denmark on October 7-11. Details of the ESMO poster presentations are as follows:

Title: A phase 1b/2 study of the nanoparticle-drug conjugate CRLX101 in combination with weekly paclitaxel in patients with platinum-resistant ovarian cancer
Date and time: Saturday, October 8 - 13:00 to 14:00 pm Central European Time
Abstract number: 1483
Location: Hall E
Poster board number: 864P
Summary: CRLX101 is an investigational NDC containing the payload camptothecin. This Phase 1b/2 trial evaluates the potential synergy of CRLX101, a topoisomerase 1 inhibitor, in combination with paclitaxel, a standard of care taxane, in patients with platinum-resistant ovarian cancer (PROC). In this trial, CRLX101 is dosed every other week at 12 or 15 mg/m^2 in conjunction with weekly paclitaxel at 80 mg/m^2. Data from the nine patients in the Phase 1b portion of the trial suggest CRLX101 administered every other week in combination with weekly paclitaxel demonstrate antitumor activity. Additionally, the combination has been generally well tolerated with no dose-limiting toxicities reported. Early data from the first nine patients in the Phase 2 portion of the trial also show activity and tolerability.

Title: Evaluation of weekly dosing of CRLX101 alone and in combination with bevacizumab in patients with advanced solid tumors
Date and time: Monday, October 10 - 13:00 to 14:00 pm Central European Time
Abstract number: 1781
Location: Hall E
Poster board number: 393P
Summary: CRLX101, an investigational NDC containing the payload camptothecin, has been shown to be active in different tumor types as a topoisomerase 1 inhibitor. This study evaluated the dosing and tolerability of a weekly dosing schedule of CRLX101 alone and in combination with bevacizumab. In arm 1, CRLX101 was administered intravenously as a monotherapy at 12 or 15 mg/m^2 weekly; in arm 2, this same dosing regimen was administered in combination with every other week dosing of bevacizumab at 10 mg/kg. In arm 1, the maximum tolerated dose for CRLX101 weekly monotherapy is 15 mg/m^2. In arm 2, the maximum tolerated dose for CRLX101 in combination with bevacizumab is either 12 mg/m^2 weekly or 15 mg/m^2 for 3 of 4 weeks. Partial responses were observed in three patients. There was increased cystitis, but no new safety concerns were observed.

Title: Pharmacokinetics of CRLX101 administered weekly in patients with advanced solid tumors
Date and time: Monday, October 10 - 13:00 to 14:00 pm Central European Time
Abstract number: 1767
Location: Hall E
Poster board number: 394P
Summary: CRLX101 is an investigational NDC containing the payload camptothecin. This study evaluated the pharmacokinetics of CRLX101 in patients with advanced solid tumors. CRLX101 was administered intravenously at 12 or 15 mg/m^2 on a weekly dosing schedule. The data suggest CRLX101 exhibits high drug retention in the plasma, slow clearance and controlled slow release of camptothecin from the NDC without drug accumulation, supporting weekly dosing of CRLX101 at 15 mg/m^2, which represents a 100% increase in dose intensity when compared to a dosing schedule of every other week.

Title: A dose-escalation study of weekly intravenous CRLX301 in patients with advanced solid tumor malignancies
Poster presentation: Monday, October 10 - 13:00 to 14:00 pm Central European Time
Abstract number: 1793
Location: Hall E
Poster board number: 413Tip
Summary: CRLX301 is an investigational NDC containing the payload docetaxel currently being investigated in a Phase 1/2a trial of patients with advanced solid tumors. The first portion of the trial determined the maximum tolerated dose for IV

CRLX301 administered every three weeks to be 75 mg/m^2. The second portion of the trial is evaluating the maximum tolerated dose for weekly administration of CRLX301. Based on data from the first portion of this trial, the weekly starting dose was 25 mg/m^2. This dose escalating trial also evaluates safety, PK and antitumor activity.

Electronic copies of the posters will be available upon request following ESMO by emailing ir@ceruleanrx.com.

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. CRLX101 has shown activity in multiple 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 400 patients. The U.S. FDA has granted CRLX101 Orphan Drug designation for the treatment of ovarian cancer, Fast Track designation in combination with paclitaxel for platinum-resistant ovarian carcinoma, fallopian tube or primary peritoneal 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 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 NDC clinical 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 NDC clinical candidate, CRLX301, is in a Phase 1/2a clinical trial. For more information, please visit http://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 the sufficiency of cash and cash equivalents to fund our operations, debt service and other scheduled expenditures 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 and completion 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 4, 2016, 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.

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Cerulean Pharma Inc.
Nicole P. Jones, 781-209-6385
Director, Investor Relations and Corporate Communications
njones@ceruleanrx.com

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