March 16, 2016

Cerulean Announces Data Presentations at the 2016 American Association for Cancer Research Annual Meeting

One Late-Breaking Poster Reporting Interim Phase 2 CRLX101 Data in Ovarian Cancer

Four Poster Presentations Featuring Preclinical and Clinical Data for CRLX101 and CRLX301

WALTHAM, Mass.--(BUSINESS WIRE)-- Cerulean Pharma Inc. (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today announced it will present interim Phase 2 CRLX101 clinical data in a late-breaking poster at the 2016 American Association for Cancer Research (AACR) Annual Meeting being held in New Orleans, Louisiana, April 16-20. The company will also present preclinical and clinical data in four poster presentations relating to its lead NDC candidates, CRLX101 and CRLX301.

"The scientific research presented by Cerulean this year at AACR continues to highlight the progress of our Dynamic Tumor Targeting™ Platform in the development of cutting-edge cancer therapies that have the potential to be more tolerable and effective," said Christopher D. T. Guiffre, President and Chief Executive Officer. "Two key highlights from the preclinical posters are that combining CRLX101 with either indoleamine 2,3-dioxygenase, or IDO, inhibitors or DNA damage response inhibitors greatly improves anti-tumor activity as compared to monotherapy. We therefore plan to explore the mechanistic basis for the observed combination responses, and use that information to guide CRLX101 clinical strategy in the setting of chemo-immunotherapy and DNA damage response regimens. Overall, the data generated from the research highlighted at AACR provide a strong rationale for continued development of CRLX101 and in patients living with cancer."

Details of the AACR poster presentations are as follows:

Late-Breaking Poster Presentation

Title: Phase 2 trial of the NDC CRLX101 in combination with Avastin® in patients with platinum-resistant Ovarian Cancer (PROC)
Date and Time: Tuesday, April 19 - 8:00 am to 12:00 pm
Abstract number: CT090
Location: Section 13
Poster board number: 18

Poster Presentations

Title: Tumor selective localization of CRLX101, an investigational nanoparticle-drug conjugate of camptothecin
Date and time: Monday, April 18 - 8:00 am to 12:00 pm
Abstract number: 1345
Location: Section 20
Poster board number: 4
Summary: CRLX101, an investigational nanoparticle-drug conjugate (NDC) containing the payload camptothecin, is currently being evaluated in multiple treatment-refractory solid tumors. In preclinical models, CRLX101 has demonstrated its ability to release camptothecin in the tumor in a slow and prolonged manner due to its long circulation half-life, and has shown striking anti-tumor activity in several different tumor models. This study sought to mechanistically dissect the process of CRLX101's entry and accumulation into tumor cells. In this study, researchers demonstrate that macropinocytosis and activation of actin polymerization play a role in the process by which tumor cells take up CRLX101. Using confocal microscopy, researchers were able to detect camptothecin fluorescence in CRLX101-treated tumor cells that co-localize with intact nanoparticles, and were able to visualize the distance traversed by CRLX101 from the tumor vasculature over time. These data are an important step forward in understanding the precise mechanism(s) underlying selective delivery of CRLX101 into tumor tissue.

Title: Pharmacokinetics (PK) of CRLX301, a Novel Nanoparticle-Drug Conjugate (NDC) Containing the Payload Docetaxel, in Patients with Refractory Solid Tumors
Date and time: Monday, April 18 - 1:00 to 5:00 pm
Abstract number: 2047
Location: Section 14
Poster board number: 19

Summary: CRLX301 is an investigational NDC containing the payload docetaxel. This study evaluated CRLX301 PK in a phase 1 study in patients with refractory solid tumors. CRLX301 was administered at 7.5, 15, 30, 60 and 75 mg/m^2 IV over 1 h every 21 days. PK studies were performed and compared to a prior PK study of Taxotere® at 75 mg/m^2 IV x 1 every 21 days (Zamboni, et al. CCP 2011). The data suggest that CRLX301 exhibits PK advantages over Taxotere such as higher retention of drug in plasma, slower clearance and controlled slow release of docetaxel from the NDC. It is anticipated that this unique PK profile of CRLX301 may improve efficacy and tolerance when compared to Taxotere. The study continues with dose escalation to further explore the safety, efficacy and PK of CRLX301.

Title: CRLX101, an investigational nanoparticle-drug conjugate of camptothecin, demonstrates synergy with immunotherapy agents in preclinical models
Date and time: Tuesday, April 19 - 8:00 am to 12:00 pm
Abstract number: 3209
Location: Section 25
Poster board number: 6
Summary: CRLX101 has been shown preclinically to be active in many different tumor types as a dual inhibitor of topoisomerase 1 and hypoxia-inducible factor 1α (HIF-1α), which is believed to control the expression of the immune-suppressive molecule PD-L1. Since CRLX101 is a potent inhibitor of HIF-1α, it is possible that it would behave as an inhibitor of the PD-1/PD-L1 axis *in vivo*. This study sought to combine CRLX101 with agents that are being investigated in combination with the anti PD-1 antibody to determine if increased efficacy could be observed. Using syngeneic tumor models, Cerulean researchers tested the combination of CRLX101 with three different IDO inhibitors (NLG919, INCB024360 and indoximod). When CRLX101 was combined with any of the three IDO inhibitors, the anti-tumor activity was greatly improved compared to monotherapy. This improved combination response was not observed in IDO inhibitor combinations with the clinically approved topoisomerase inhibitor irinotecan, suggesting that CRLX101 may provide a unique advantage in this context. Of particular note, CRLX101/IDO inhibitor combination was also superior to the combination of anti-PD-1 antibody and IDO inhibitor. These data suggest that CRLX101 in combination with IDO inhibitors can successfully block host-mediated immune-suppression to enhance anti-tumor immunity, and this combination may therefore show improved therapeutic activity in the clinic.

Title: A camptothecin-containing nanoparticle-drug conjugate combination with DDR agents provides a novel approach to increasing therapeutic index
Poster presentation: Tuesday, April 19 - 1:00 to 5:00 pm
Abstract number: 3721
Location: Section 14
Poster board number: 14
Summary: Topoisomerase I inhibitors are used as standard-of-care chemotherapy in many types of cancer but are associated with significant toxicities. There is potential to improve their efficacy further by combining with a PARP inhibitor, such as olaparib, but subsequent trials have shown dose limiting myelotoxicity. This study explored the molecular mechanism and therapeutic potential of combining CRLX101 with either olaparib or the WEE1 inhibitor AZD1775, by testing efficacy and safety in preclinical models. Collectively, these preclinical data demonstrate increased anti-tumor efficacy of CRLX101 when combined with DDR inhibitors, while mitigating much of the combined bone marrow toxicity through sequenced schedules. The combination schedule for CRLX101 and olaparib identified in Cerulean's preclinical models as providing an increased therapeutic index has been used to develop clinical protocols to test this combination in a second-line (relapsed) small cell lung cancer clinical trial, which is being conducted in collaboration with the National Cancer Institute.

Electronic copies of the posters will be available upon request following AACR 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, 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 350 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 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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 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.

Avastin is a registered trademark of Genentech, Inc.

Taxotere is a registered trademark of Sanofi and/or its consolidated subsidiaries.

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