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Cerulean Announces Results from Phase 2 Clinical Trial of CRLX101 and Avastin® Combination in Relapsed Renal Cell Carcinoma

CRLX101 plus Avastin Does Not Show Improvement Compared to Standard of Care in this Setting

Company to Host Conference Call Today at 4:30 pm EDT

WALTHAM, Mass.--(BUSINESS WIRE)-- Cerulean Pharma Inc. (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today announced top-line results from the Company's Phase 2, randomized, multi-center clinical trial of its lead candidate, CRLX101, in combination with Avastin® (bevacizumab) in the treatment of patients with advanced renal cell carcinoma (RCC).

The trial was conducted at 43 sites in the US and South Korea, and enrolled 115 patients with RCC who progressed through two or three prior lines of therapy. Patients were randomized to receive CRLX101 in combination with Avastin or investigator's choice standard of care (SOC) therapy. SOC agents included axitinib, bevacizumab, everolimus, pazopanib, sorafenib, sunitinib, and temsirolimus. The primary endpoint was progression free survival (PFS) in the clear cell population (n=102) assessed by independent radiological review. Secondary endpoints included overall response rate, duration of response and overall survival.

The study demonstrated no statistically significant difference in median PFS and objective response rate for the CRLX101 combination compared to SOC. Median PFS was 3.7 months for the CRLX101 combination compared with a median PFS of 3.9 months for SOC (hazard ratio: 1.25, p=0.822). The 95% confidence interval for PFS for the CRLX101 combination was 2.0 months to 4.3 months and for SOC was 2.2 months to 5.4 months. Objective response rate by independent radiological review for patients who received the CRLX101 combination was 5% (2/42) compared to 14% (6/43) for SOC (p=0.836). The CRLX101 and Avastin combination appeared to be safe and well-tolerated and the safety and tolerability profile of the combination was consistent with that observed in previous studies. The full data set from the trial are expected to be submitted for presentation at an upcoming medical conference.

"We are disappointed with this outcome and will undertake a thorough analysis of the data to understand why CRLX101 plus Avastin underperformed compared to the results we saw in an earlier investigator-sponsored trial," said Christopher D. T. Guiffre, President and Chief Executive Officer of Cerulean. "This outcome did not support our hypothesis that targeting hypoxia inducible factor (HIF) in combination with VEGF inhibitor in RCC, a HIF-overexpressing tumor type, would be beneficial, so we will not pursue HIF as a target going forward. We will continue to focus on the potent topoisomerase 1 inhibition of CRLX101's payload, camptothecin, in topoisomerase 1-sensitive tumors. Our combinations with weekly paclitaxel and LYNPARZA™ (olaparib) are examples of ongoing trials that leverage CRLX101's topoisomerase 1 inhibition in combination with chemotherapies and DNA damage repair agents."

Conference Call Details

Cerulean will host a conference call today at 4:30 pm Eastern Daylight Time to discuss the results and provide an update on the CRLX101 development program. The call can be accessed by dialing (844) 831-3031 or (443) 637-1284 prior to the start of the call and referencing conference ID: 67807137. The conference call will also be webcast live over the Internet and can be accessed on the "Investors" section of the Cerulean website, www.ceruleanrx.com. The webcast will be available on Cerulean's website for two weeks.

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 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 Phase 2a clinical development. 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 the sufficiency of our 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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