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Cerulean Announces Phase 1b/2 Trial of CRLX101 in Combination with Avastin® in Relapsed Renal Cell Carcinoma Meets Primary Endpoint

Preliminary top-line data demonstrate a median PFS of 9.9 months - current standard of care is approximately 3.5 months

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Cerulean Pharma Inc. (Nasdaq: CERU), a leader in Dynamic Tumor Targeting™, today announced that a Phase 1b/2 trial of its lead nanoparticle-drug conjugate, CRLX101, in combination with Avastin® in relapsed renal cell carcinoma (RCC) achieved its primary endpoint of at least 50% of patients achieving four months of progression free survival (PFS). Data from this trial have been submitted for presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting (May 29-June 2, 2015) and will be submitted for publication in a peer-reviewed journal later this year.

Notably, as of the ASCO submission (February 3, 2015), preliminary top-line data from this trial showed a median PFS of 9.9 months. The current standard of care in the 3rd and 4th line setting for the treatment of relapsed RCC provides approximately 3.5 months of PFS[1]. As of the ASCO submission, the RECIST response rate from this trial was 23%. Standard of care in this setting provides a 2-4% response rate[1]. In this trial, CRLX101 and Avastin have been generally well tolerated with no unexpected toxicities.

"The top-line results from this trial in a difficult-to-treat patient population are encouraging," said Paul Friedman, M.D., Executive Chairman at Cerulean. "The median PFS of 9.9 months supports the rationale for our ongoing randomized Phase 2 trial of CRLX101 plus Avastin in 3rd and 4th line RCC."

The ongoing 22-patient Phase 1b/2 study in relapsed RCC is an investigator-sponsored trial conducted at the University of Pennsylvania and Thomas Jefferson University Hospital with support from Cerulean. The last patient was enrolled in December 2014. Seven patients were still being treated at the time of the ASCO submission.

Cerulean's ongoing randomized Phase 2 trial in 3rd and 4th line RCC is a company-sponsored trial being conducted at approximately 30 U.S. centers. Up to 110 patients will be enrolled. Up to 90 patients (45 in the treatment arm and 45 in the comparator arm) with clear cell RCC will be assessed to determine if the trial meets its primary endpoint. Up to 20 patients with non-clear cell RCC will be evaluated separately for response rate and PFS. For the primary endpoint, the trial is powered to show a 2.3-month improvement in median PFS over an expected 3.5 months in the comparator arm. Cerulean expects to release top-line primary endpoint data and overall response rate data from this trial in the second quarter of 2016.

Reference:

1. Motzer, RJ. *Dovitinib versus sorafenib for third-line targeted treatment of patients with metastatic renal cell carcinoma: An open-label, randomized Phase 3 trial*. Lancet Oncol. 2014 Mar;15(3):286-96.

About CRLX101

CRLX101 is a dynamically tumor-targeted 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 hypoxia-inducible factor-1α (HIF-1α), which research suggests is a master regulator of cancer cell survival mechanisms thought to promote drug and radiation resistance. CRLX101 has shown activity in four different tumor types, both as monotherapy and in combination with other cancer treatments. CRLX101 is currently in Phase 2 clinical development and has been dosed in more than 250 patients.

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 superior to 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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 19, 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 trademark of Genentech, Inc.

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