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Cerulean Announces Presentation of Full Data from Phase 1b/2 Trial of CRLX101 in Combination with Avastin® in Metastatic Renal Cell Carcinoma at the Annual Meeting of the American Society for Clinical Oncology

Unequivocal activity and encouraging progression-free survival demonstrated in 2nd through 6th line patients, including RECIST responses in both clear cell and non-clear cell patients

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Cerulean Pharma Inc. (Nasdaq: CERU) today announced that full data from a Phase 1b/2 investigator-sponsored trial of CRLX101 in combination with Avastin® (bevacizumab) in metastatic renal cell carcinoma, or RCC, was presented at the 2015 American Society of Clinical Oncology Annual Meeting, or ASCO.

In addition, three CRLX101 trials in progress posters were presented at ASCO describing a randomized Phase 2 trial of CRLX101 in combination with Avastin in patients with 3rd and 4th line RCC, a Phase 2 trial of CRLX101 in combination with Avastin in patients with 2nd and 3rd line platinum-resistant ovarian cancer, and a Phase 1b/2 trial of CRLX101 in combination with chemoradiotherapy, or CRT, in the neoadjuvant treatment of newly diagnosed rectal cancer.

Highlights from the ASCO posters include:

Phase 1b/2 trial evaluating CRLX101 in combination with Avastin in treatment-refractory metastatic renal cell carcinoma

Presented by Principal Investigator, Stephen Keefe, M.D., Abramson Cancer Center, University of Pennsylvania

- Phase 1b/2 investigator-sponsored trial, or IST, being conducted at two U.S. cancer centers in patients with metastatic RCC
- 2nd through 6th line patients (n=22)
- Primary endpoint (50% of patients achieving ≥ 4 months progression free survival, or PFS) met with 12/22 patients achieving ≥ 4 months PFS
- Median PFS observed among all patients was 9.9 months including:
  - 11.21 months among 2nd line patients (n=4)
  - 7.59 months among 3rd through 6th line patients (n=18)
- Overall response rate, or ORR, observed among all patients was 23% including:
  - 1 partial response (PR) in 2nd line patients (25% ORR)
  - 4 PRs in 3rd through 6th line patients (22% ORR)
  - 3 PRs among patients with clear cell histology
  - 2 PRs among patients with non-clear cell histology
  - Average durability of response was 3.5 months from PR to time off study
- Consistent with Phase 1 results presented at ASCO 2014, combination of CRLX101 and Avastin continues to be generally well tolerated with no dose limiting toxicities observed

As of May 2015, two patients remain active on study in cycles 8 and 11 respectively. Final data from this trial will be submitted for publication in a peer-reviewed journal later this year. Cerulean is enrolling a randomized Phase 2 clinical trial of CRLX101 in combination with Avastin in 3rd and 4th line RCC patients.

Randomized Phase 2 trial evaluating CRLX101 in combination with Avastin in 3rd and 4th line RCC versus standard of care

Presented by Principal Investigator, Martin Voss, M.D., Memorial Sloan Kettering Cancer Center

- Randomized Phase 2 clinical trial being conducted at 38 U.S. and 5 South Korean cancer centers in patients with advanced, unresectable metastatic RCC who have completed 2 or 3 prior regimens of therapy
- Primary endpoint will compare PFS among 90 clear cell RCC patients treated with concurrently administered CRLX101 plus Avastin versus investigator's choice of standard of care
- Primary endpoint will employ a blinded independent radiographic review in order to ensure clinical trial integrity
- Statistical power is set at 80% to detect an increase in mPFS from 3.5 months to 5.8 months with a hazard ratio of 0.6
- Secondary/exploratory endpoints include overall survival, ORR, safety, pharmacokinetics, and plasma biomarkers
- 20 patients with non-clear cell RCC histology will be evaluated independently
- Enrollment of 110 patients is ongoing and is expected to be complete by Autumn 2015
- CRLX101 in combination with Avastin has been granted Fast Track designation in metastatic RCC by the U.S. Food and Drug Administration

Phase 2 trial evaluating CRLX101 in combination with Avastin in recurrent platinum-resistant ovarian cancer

Presented by Principal Investigator, Carolyn Krasner, M.D., Massachusetts General Hospital, Harvard Medical School

- Phase 2 IST being conducted at three U.S. cancer centers in patients with platinum resistant ovarian cancer who have received 1 or 2 prior regimens of chemotherapy
- Primary endpoint is rate of PFS at 6 months
- Secondary endpoints are ORR and assessment of toxicity

Phase 1b/2 trial evaluating CRLX101 in combination with CRT in neoadjuvant treatment of newly diagnosed rectal cancer

Presented by Principal Investigator, Andrew Wang, M.D., Lineberger Comprehensive Cancer Center, University of North Carolina-Chapel Hill

- Phase 1b/2 IST being conducted at six U.S. cancer centers in patients with non-metastatic rectal cancer who have received no prior therapy
- Objectives of this trial include:
  - Define the rate of pathologic complete response, or pCR, among patients receiving CRLX101 in combination with CRT
  - Characterize the safety and toxicity profile of this combination
  - Estimate disease-free survival, or DFS, and overall survival, or OS
  - Explore changes in HIF-1α and other plasma biomarkers
  - Explore the association between baseline tumor biomarkers and pCR

Electronic copies of these posters are available upon request 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 250 patients. The U.S. FDA had 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 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, 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 May 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.

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