



August 4, 2016

## Cerulean Reports Second Quarter 2016 Corporate Highlights and Financial Results

*Conference Call Today at 4:30 p.m. ET*

WALTHAM, Mass.--(BUSINESS WIRE)-- [Cerulean Pharma Inc.](#) (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today provided an update on corporate activities for the quarter ended June 30, 2016.

"Since our last quarterly call, we made significant progress advancing both of our clinical candidates, CRLX101 and CRLX301," said Christopher D. T. Guiffre, President and Chief Executive Officer of Cerulean. "We reached the 70 events needed to lock the database for our randomized Phase 2 trial in 3<sup>rd</sup> and 4<sup>th</sup> line renal cell carcinoma (RCC). Therefore, we remain on track to report top-line data this quarter. In addition, we presented compelling data from our Phase 1b/2 trial of CRLX101 with weekly paclitaxel in relapsed ovarian cancer, and subsequent to the end of the quarter, the FDA granted Fast Track designation for this promising combination. We believe CRLX101 has broad clinical utility as both monotherapy and in combination with other anti-cancer agents against a broad range of tumor types, and we look forward to providing updates on our continued clinical progress in the months ahead."

### Second Quarter 2016 Corporate Highlights

- | Presented data from a Phase 1b/2 trial of CRLX101 in combination with weekly paclitaxel in platinum-resistant ovarian cancer at the Experts Meeting on Gynecologic Oncology 2016
  - | Five of the nine (56%) Phase 1b patients achieved a partial response, with one complete disappearance of tumor by imaging but detectable CA125 levels
  - | Three of the five patients (60%) who had previously failed Avastin achieved a partial response
- | Presented data from a Phase 2 trial of CRLX101 in combination with Avastin in platinum-resistant ovarian cancer at the 2016 American Association for Cancer Research (AACR) annual meeting
  - | 17 of the 18 patients (94%) achieved a partial response or stable disease
  - | 10 of the 18 patients (56%) achieved six months of progression-free survival
- | AstraZeneca presented data from its preclinical studies of CRLX101 in combination with LYNPARZA™ (olaparib) at the 2016 AACR annual meeting
  - | Identified bone marrow-sparing dosing schedule for use in current Phase 1/2 trial
  - | Observed synergistic activity compared to either monotherapy in a BRCA wild type small cell lung cancer xenograft model
- | Dosed first patient in a Phase 1/2 trial evaluating CRLX101 in combination with LYNPARZA in patients with advanced solid tumors
- | Published data in *Annals of Oncology* from 22 metastatic RCC patients treated with CRLX101 in combination with Avastin® (bevacizumab) in Phase 1b/2 investigator-sponsored trial
- | Published data in *Cancer Research* highlighting preclinical proof of concept of CRLX101 in combination with Avastin in models of metastatic triple-negative breast cancer
- | Presented data from a Phase 1/2a trial of CRLX301 at the 2016 American Society of Clinical Oncology (ASCO) annual meeting
  - | Generally well tolerated in Phase 1 with early hints of antitumor activity and differentiated pharmacokinetics compared to docetaxel
- | Announced first patient dosed in Phase 2a evaluating CRLX301 in patients with advanced solid tumors

### Second Quarter 2016 Financial Summary

Cash Position - The Company had \$47.2 million in cash and cash equivalents at June 30, 2016. The Company believes its cash and cash equivalents are sufficient to fund its planned operations into the second quarter of 2017 and that the Company has the ability to reduce or defer operating expenses as may be needed to fund its operations into the third

quarter of 2017.

R&D Expenses - Research and development expenses for the second quarter were \$7.5 million, compared to \$6.7 million for the same period in 2015. The increase was due primarily to increased expenses related to increased chemistry, manufacturing and control expenditures to support current and future clinical development partially offset by lower costs for ongoing clinical development programs.

G&A Expenses - General and administrative expenses for the second quarter were \$2.8 million, compared to \$2.7 million for the same period in 2015.

Net Loss Attributable to Common Stockholders - Net loss attributable to common stockholders for the second quarter was \$10.9 million, compared to net loss attributable to common stockholders of \$9.9 million for the same period in 2015.

More detailed financial information and analysis may be found in our Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission on August 4, 2016.

### **Key Developments Subsequent to the End of the Second Quarter**

- ┆ Received Food and Drug Administration Fast Track designation for CRLX101 in combination with paclitaxel, for the treatment of platinum-resistant ovarian carcinoma, fallopian tube or primary peritoneal cancer

### **Anticipated Upcoming Milestones**

During the second half of 2016, Cerulean expects to:

- ┆ Report top-line data (PFS and ORR) from a randomized Phase 2 trial of CRLX101 in combination with Avastin in 3<sup>rd</sup> and 4<sup>th</sup> line metastatic RCC
- ┆ Present data from the second group of patients from a Phase 1b/2 trial of CRLX101 in combination with weekly paclitaxel in platinum-resistant ovarian cancer at the 2016 European Society for Medical Oncology (ESMO) Congress
- ┆ Present data from an ongoing Phase 1 trial evaluating weekly dosing of CRLX101 at ESMO

### **Conference Call Information**

Management will conduct a conference call at 4:30 p.m. (ET) today to provide a business update and review Cerulean's second quarter financial results. 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: 46517856. The conference call also will be webcast live over the Internet and can be accessed on the "Investors" section of the Cerulean website, [www.ceruleanrx.com](http://www.ceruleanrx.com). The webcast will be archived 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, and also inhibits hypoxia-inducible factor-1 $\alpha$  (HIF-1 $\alpha$ ), 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, 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<sup>®</sup> 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 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 Phase 2a clinical development. For more information, please visit [www.ceruleanrx.com](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.

### **About GOG Foundation, Inc.**

The GOG Foundation, Inc. (GOG Foundation) is an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. Continuous evaluation of the GOG Foundation's processes is utilized in order to constantly improve the quality of patient care. The GOG Foundation conducts clinical trials for patients with a variety of gynecologic malignancies, including cancers that arise from the ovaries, uterus, cervix, vagina, and vulva. The GOG Foundation is a separate entity from the National Clinical Trials Network groups that are funded by the National Cancer Institute.

### **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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LYNPARZA is a trademark of the AstraZeneca group of companies.

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