



May 6, 2015

Cerulean Reports First Quarter 2015 Corporate Highlights and Financial Results

Phase 1b/2 trial of CRLX101 in combination with Avastin® in metastatic renal cell carcinoma achieved primary endpoint

CRLX101 in combination with Avastin granted Fast Track designation in metastatic renal cell carcinoma

Data from randomized Phase 2 trial of CRLX101 in combination with Avastin in metastatic renal cell carcinoma expected in second quarter 2016

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Cerulean Pharma Inc.](http://www.ceruleanpharma.com) (Nasdaq: CERU) today provided an update on corporate activities during the quarter ended March 31, 2015, and reported progress with its clinical development programs.

"In the first quarter, Cerulean announced that a Phase 1b/2 trial of CRLX101 in combination with Avastin in metastatic renal cell carcinoma, or RCC, achieved its primary endpoint," said Christopher D. T. Guiffre, Cerulean's President & Chief Executive Officer. "Notably, this ongoing trial is showing 9.9 months of median progression free survival, or PFS, in a setting where the standard of care provides about 3.5 months PFS. These data give us confidence in our ongoing randomized Phase 2 trial of CRLX101 in combination with Avastin in 3rd and 4th line RCC, which is powered to show a 2.3 month improvement over an expected 3.5 months PFS from standard of care."

Guiffre continued, "Shortly after the end of the quarter, Cerulean completed a public stock offering which generated approximately \$40.3 million in gross proceeds. The additional capital extends our cash runway into 2017 and puts us in a strong position to further advance the clinical development of CRLX101 and CRLX301. Our momentum continued with the Food and Drug Administration's Fast Track designation for CRLX101 in combination with Avastin in metastatic RCC in patients who have progressed through two or three prior lines of therapy."

First Quarter 2015 Corporate Highlights

- Closed debt facility for up to \$26.0 million with, and sold \$1.0 million of Cerulean common stock in a private placement to, Hercules Technology Growth Capital, Inc.
- Executed clinical research agreement with GOG Foundation, Inc., to study CRLX101 in combination with weekly paclitaxel in patients with relapsed ovarian cancer
- Achieved primary endpoint in Phase 1b/2 IST of CRLX101 in combination with Avastin in patients with metastatic RCC
- Reported interim data from ongoing Phase 2 IST of CRLX101 in combination with Avastin in patients with relapsed ovarian cancer
- Reported interim data from ongoing Phase 1b/2 IST of CRLX101 in combination with chemoradiotherapy, or CRT, in patients with non-metastatic rectal cancer
- Appointed Tiffany Crowell as Vice President, Clinical Operations
- Promoted Christopher D. T. Guiffre, J.D., M.B.A., to President & Chief Executive Officer

Key Subsequent Events

- Closed underwritten public offering of common stock which generated approximately \$40.3 million in gross proceeds in April 2015, including full exercise of the underwriters' overallotment option
- Granted Fast Track designation by the FDA for CRLX101 in combination with Avastin in metastatic RCC in patients who have progressed through two or three prior lines of therapy

Anticipated Upcoming Milestones

During the remainder of 2015, Cerulean expects to:

- Present full data for Phase 1b/2 IST of CRLX101 in combination with Avastin in metastatic RCC through Principal Investigator, Stephen Keefe, M.D., at 2015 American Society for Clinical Oncology, or ASCO, Annual Meeting
- Host a reception at ASCO on June 1 with the Principal Investigators of the Phase 1b/2 and randomized Phase 2 trials for investors, analysts, and media
- Report updated results from ongoing Phase 2 IST of CRLX101 in combination with Avastin in relapsed ovarian cancer
- Report updated results from ongoing Phase 1b/2 IST of CRLX101 in combination with CRT in non-metastatic rectal cancer
- Report initial clinical results from ongoing Phase 1 trial of CRLX301

In 2016, Cerulean expects to:

- Report clinical results from planned Phase 1b trial with GOG Foundation of CRLX101 in combination with weekly paclitaxel in relapsed ovarian cancer
- Report primary and secondary endpoint data from Phase 2 randomized RCC trial
- Initiate Phase 2a trial of CRLX301 in patients with selected solid tumors

Brief Financial Summary

As of March 31, 2015, Cerulean had cash and cash equivalents of \$56.3 million. In addition, in April 2015, the Company closed an underwritten public offering of common stock which generated approximately \$40.3 million in gross proceeds. Cerulean estimates that its current cash and cash equivalents will fund operations into 2017.

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 May 6, 2015.

Conference Call Information

Christopher D. T. Guiffre, J.D., M.B.A., President & Chief Executive Officer, and Paul Friedman, M.D., Executive Chairman, will conduct a conference call at 4:30 p.m. (ET) today to provide a business update and review the Company's first-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: 33646103. 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 archived on the Company'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 α (HIF-1 α), 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 currently in Phase 2 clinical development and has been dosed in more than 250 patients and has 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, 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 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.

Avastin® is a trademark of Genentech, Inc.

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