



November 13, 2014

## Cerulean Reports Third-Quarter 2014 Corporate Highlights and Financial Results

CAMBRIDGE, Mass., Nov. 13, 2014 (GLOBE NEWSWIRE) -- [Cerulean Pharma Inc.](#) (Nasdaq:CERU), a leader in Dynamic Tumor Targeting™, today provided an update on corporate activities during the quarter ended September 30, 2014.

"Cerulean launched an important randomized Phase 2 trial in the third quarter," said Paul A. Friedman, M.D., Executive Chairman of Cerulean. "We are studying the combination of CRLX101 and Avastin® (bevacizumab) versus standard of care in 3<sup>rd</sup> and 4<sup>th</sup> line renal cell carcinoma, or RCC. The randomized trial follows provocative Clinical Proof of Principle data from a single-arm investigator-sponsored trial, or IST, where investigators observed a 27% objective response rate, or ORR, in the first 11 patients evaluated in that study. Unlike 1<sup>st</sup> and 2<sup>nd</sup> line RCC, where multiple TKIs and mTOR inhibitors are approved, 3<sup>rd</sup> and 4<sup>th</sup> line RCC is an area of high unmet medical need, where patients typically are treated with yet another TKI or an mTOR inhibitor after becoming resistant to another drug from the same class. We believe a new option is needed in 3<sup>rd</sup> and 4<sup>th</sup> line RCC, and we are eager to learn if our Clinical Proof of Principle data will be confirmed in a randomized trial. Patient enrollment has begun, and we look forward to announcing ORR data from the randomized trial by the end of 2015."

Dr. Friedman continued, "We also expect to announce data for CRLX101 from two single-arm ISTs that could provide Clinical Proof of Principle in two additional indications, ovarian and rectal cancer, by the end of the first quarter of 2015. Finally, we anticipate Phase 1 data for our second platform-generated candidate, CRLX301, by the end of 2015."

### Third Quarter 2014 Corporate Highlights

- Launched a randomized Phase 2 clinical trial
  - This trial studies CRLX101 in combination with Avastin versus standard of care in 3<sup>rd</sup> and 4<sup>th</sup> line RCC, an area of high unmet medical need
  - This trial follows Clinical Proof of Principle from a single-arm IST of CRLX101 plus Avastin - in the first 11 patients, the combination provided mPFS of 7.6 months (versus 3.6-4.9 months for standard of care in this setting) and a 27% ORR (versus 2-4% for standard of care in this setting)
  - This trial is guided by a steering committee, including Robert Figlin, M.D. (Cedars-Sinai Medical Center), Thomas Hutson, D.O., Pharm.D. (Baylor Charles A. Sammons Cancer Center), Stephen Keefe, M.D. (Abramson Cancer Center of the University of Pennsylvania), Robert Motzer, M.D. (Memorial Sloan Kettering Cancer Center), and Nicholas Vogelzang, M.D. (Comprehensive Cancer Centers of Nevada)
- Announced the appointment of Alejandra Carvajal, J.D., as Vice President & General Counsel

### Key Subsequent Events

- Announced the appointments of Paul Friedman, M.D., as Executive Chairman of the Board of Directors and Christopher Guiffre, J.D., MBA, as Chief Operating Officer, following the resignation of Oliver Fetzner, Ph.D., MBA, as Chief Executive Officer
- Announced the appointments of Susan Kelley, M.D., and David Parkinson, M.D., to the Board of Directors
- Announced the appointment of Pamela Strode, M.S., as Vice President of Regulatory Affairs

### Anticipated Upcoming Milestones

During the remainder of 2014 and in 2015, Cerulean plans to:

- Initiate a Phase 1 clinical trial of CRLX301, the second candidate from Cerulean's Dynamic Tumor Targeting Platform, by the end of 2014
- Announce clinical data in the first quarter of 2015 from an ongoing IST of CRLX101 in relapsed ovarian cancer to support a 'go / no go' decision for advancement into a randomized trial
- Announce clinical data in the first quarter of 2015 from an ongoing IST of CRLX101 in non-metastatic rectal cancer to support a 'go / no go' decision for advancement into a randomized trial
- Announce clinical data in the second quarter of 2015 from the final 11 patients in an ongoing IST of CRLX101 in relapsed RCC
- Announce clinical data in the fourth quarter of 2015 from a planned Phase 1 trial of CRLX301
- Announce clinical data in the fourth quarter of 2015 from a randomized Phase 2 trial of CRLX101 in relapsed RCC

## Brief Financial Summary

As of September 30, 2014, Cerulean had cash and cash equivalents of \$57.8 million. Cerulean estimates that its current cash and cash equivalents will allow it to fund the ongoing randomized Phase 2 clinical trial of CRLX101 in RCC, the Phase 1 clinical trial of CRLX301, and ongoing ISTs of CRLX101.

More detailed financial information and analysis may be found in the Company's Quarterly Report on [Form 10-Q](#), which was filed with the Securities and Exchange Commission on November 13, 2014.

## Conference Call Information

Paul Friedman, M.D., Executive Chairman and Chris Guiffre, Chief Operating Officer will conduct a conference call at 4:30 p.m. (ET) today to provide a business update and review the Company's third-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: 25500996. 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](http://www.ceruleanrx.com). The webcast will be archived on the Company's website for two weeks.

## 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-1 $\alpha$  (HIF-1 $\alpha$ ), which research suggests is a master regulator of cancer cell survival mechanisms thought to promote drug and radiation resistance. CRLX101 has shown activity in late-stage disease in three different tumor types, both as monotherapy and in combination with Avastin®. CRLX101 is currently in Phase 2 clinical development and has been dosed in more than 250 patients.

## 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 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 nanoparticle-drug conjugates, or NDCs, designed to selectively attack tumor cells, reduce toxicity by sparing the body's normal cells, and enable therapeutic combinations. Our lead product candidate, CRLX101, is in multiple clinical trials in combination with other cancer treatments, all of which aim to unlock the power of combination therapy. For more information, please visit [www.ceruleanrx.com](http://www.ceruleanrx.com).

## 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," "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 November 13, 2014 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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Source: Cerulean Pharma Inc.

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