



August 12, 2014

Cerulean Reports Second Quarter 2014 Corporate Highlights and Financial Results

CAMBRIDGE, Mass., Aug. 12, 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 June 30, 2014.

"In the second quarter, Cerulean became a public company, raising money to conduct clinical trials of our first two platform-generated product candidates," said Oliver S. Fetzer, Ph.D., President and Chief Executive Officer of Cerulean. "Our lead candidate, CRLX101, has shown activity in multiple tumor-types, as both monotherapy and in combination with other cancer treatments, and it has been well tolerated in more than 200 patients to date. We are conducting CRLX101 trials in three tumor types: relapsed renal cell carcinoma, or RCC, relapsed ovarian cancer, and non-metastatic rectal cancer."

"Our second candidate, CRLX301, is expected to enter the clinic by year-end," continued Dr. Fetzer. "Both of our candidates are nanoparticle-drug conjugates, or NDCs, that are designed to selectively attack tumor cells, reduce toxicity by sparing the body's normal cells, and enable therapeutic combinations."

Dr. Fetzer also summarized anticipated timelines for the announcement of clinical results. "We anticipate announcing data from two ongoing single-arm CRLX101 trials in the first quarter of 2015, data from an ongoing randomized CRLX101 trial by the end of 2015, and data from a planned Phase 1 CRLX301 trial by the end of 2015."

Second Quarter 2014 Corporate Highlights

- Completed IPO
 - Raised net proceeds of \$59.9M, including the exercise of the underwriters' over-allotment option
 - Key uses of proceeds include a randomized Phase 2 clinical trial of CRLX101 in relapsed RCC, a single-arm Phase 2 clinical trial of CRLX101 in relapsed ovarian cancer, a single-arm Phase 1b/2 clinical trial of CRLX101 in non-metastatic rectal cancer, and a planned Phase 1 clinical trial of CRLX30
- Reported CRLX101 data at the ASCO 50th Annual Meeting
 - "*HIF inhibition in mRCC: Planned interim analysis of CRLX101 with bevacizumab, a phase 1b/2a study*", Abstract #e15611, previously presented at ASCO GU and included in electronic abstract compendium for ASCO annual meeting
 - "*Phase II clinical trial evaluating CRLX101 in recurrent ovarian, tubal, and peritoneal cancer*", Abstract #5581
 - "*A phase 1b/2 study of neoadjuvant chemoradiotherapy with CRLX101 and capecitabine for locally advanced rectal cancer*", Abstract #TPS3667
- Completed preparations for randomized Phase 2 clinical trial of CRLX101
 - This trial studies CRLX101 in combination with Avastin® (bevacizumab) versus standard of care in 3rd and 4th line RCC, an area of high unmet need
 - This trial follows Clinical Proof of Principle from single-arm Phase 1b/2 clinical trial of CRLX101 plus Avastin - in the first eleven patients, the combination provided median progression free survival of 7.6 months (versus 3.6-4.9 months for standard of care in this setting) and a 27% response rate (versus 2-4% for standard of care in this setting)
 - This trial is guided by a distinguished steering committee, including Robert Figlin, M.D. (Cedars-Sinai Medical Center), Thomas Hutson, M.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)

Key Subsequent Event

- Announced initiation of randomized Phase 2 clinical trial of CRLX101 to be conducted at approximately 30 U.S. sites

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 Proof of Principle data in relapsed ovarian cancer in the first quarter of 2015
- Announce Clinical Proof of Principle data in non-metastatic rectal cancer in the first quarter of 2015
- Announce Phase 1 data for CRLX301 in the fourth quarter of 2015
- Announce randomized Phase 2 data for CRLX101 in relapsed RCC in the fourth quarter of 2015

Brief Financial Summary

As of June 30, 2014, Cerulean had cash and cash equivalents of \$64.3 million. Cerulean estimates that its current cash and cash equivalents will allow it to fund several ongoing single-arm clinical trials of CRLX101, an ongoing randomized Phase 2 clinical trial of CRLX101, and a planned Phase 1 trial of CRLX301.

On August 12, 2014, Cerulean filed its financial results for the second quarter ended June 30, 2014, as part of its Quarterly Report on Form 10-Q, which can be accessed via the following links: <http://ir.ceruleanrx.com/sec.cfm> or www.sec.gov.

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-1a (HIF-1a), 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 200 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

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 lead product candidate, CRLX101, is in multiple clinical trials with other cancer treatments, all of which aim to unlock the power of combination therapy. 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, 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 August 12, 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.

Avastin[®] is a trademark of Genentech Inc.

CONTACT: For IR:

Heather Savelle

MacDougall Biomedical Communications

781.235.3060

hsavelle@macbiocom.com

For PR:

Laura Kempke

MSLGROUP

781.684.0770

laura.kempke@mslgroup.com