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Cerulean Receives FDA Fast Track Designation for CRLX101 for the Treatment of Platinum-Resistant Ovarian Cancer

WALTHAM, Mass.--(BUSINESS WIRE)-- [Cerulean Pharma Inc.](#) (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for Cerulean's lead nanoparticle-drug conjugate, CRLX101, in combination with paclitaxel, for the treatment of platinum-resistant ovarian carcinoma, fallopian tube or primary peritoneal cancer.

"We appreciate the FDA's acknowledgement of CRLX101's potential in an area of significant unmet medical need," said Christopher D. T. Guiffre, President and Chief Executive Officer of Cerulean. "We are encouraged by the profound treatment effect observed early in the ongoing clinical trial with the GOG Foundation, Inc. (GOG), and we look forward to working closely with the FDA as we endeavor to bring a new treatment option to women living with platinum-resistant ovarian cancer."

CRLX101 is being evaluated in combination with weekly paclitaxel for the treatment of recurrent platinum-resistant ovarian carcinoma in a Phase 1b/2 clinical trial. Data from the Phase 1b portion of the trial were the subject of an oral presentation at the Gynecologic Oncology 2016 Conference in May. These data showed that five of the first nine patients (56%) enrolled in the trial achieved partial responses. Of note, five of the nine patients enrolled in the Phase 1b trial previously failed Avastin[®] (bevacizumab) and three of these five patients achieved partial responses. Cerulean is conducting this trial in collaboration with the GOG and expects to provide an update at the European Society for Medical Oncology 2016 Congress.

In 2015, CRLX101 was granted Orphan Drug designation for the treatment of ovarian cancer.

The FDA's Fast Track Program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious conditions and that demonstrate the potential to address unmet medical needs. Drugs that receive this designation benefit from more frequent communications and meetings with FDA to review the drug's development plan, including the design of the proposed clinical trials and the extent of data needed for approval.

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 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[®] in metastatic renal cell carcinoma.

About GOG Foundation, Inc. (GOG Foundation)

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.

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.

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 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 May 2, 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.

Avastin is a registered trademark of Genentech, Inc.

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Cerulean Pharma
Nicole P. Jones, 781-209-6385
Director, Investor Relations and Corporate Communications
njones@ceruleanrx.com

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