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Cerulean Announces Oral Presentation of CRLX101 Clinical Data at Gynecologic Oncology 2016 Conference

Dr. Krasner to Present Phase 1b Results of CRLX101 in Combination with Weekly Paclitaxel in Relapsed Ovarian Cancer

WALTHAM, Mass.--(BUSINESS WIRE)-- Cerulean Pharma Inc. (NASDAQ:CERU), a clinical-stage company developing nanoparticle-drug conjugates (NDCs), today announced that Carolyn N. Krasner, M.D., of the Massachusetts General Hospital Cancer Center, will give an oral presentation on the Phase 1b results of an ongoing clinical trial of CRLX101 in combination with weekly paclitaxel in patients with relapsed ovarian cancer at the Gynecologic Oncology 2016 Conference to be held on May 19-21 in San Antonio, Texas. This trial is being conducted by Cerulean in collaboration with the GOG Foundation, Inc. under the direction of Dr. Krasner, GOG Study Chair.

"Thus far, the combination of CRLX101 and weekly paclitaxel in platinum-resistant ovarian cancer patients appears to be well tolerated. Moreover, in the first nine patients enrolled in this Phase 1b trial, we have observed that a majority have objective responses," said Dr. Krasner. "I am eager to present these results to the gynecologic oncology community at the Gynecologic Oncology 2016 Conference in May and to further discuss them with my colleagues at the GOG Foundation, Inc. Meeting in July."

As of March 11, 2016, three patients received 12 mg/m^2 of CRLX101 and six patients received 15 mg/m^2 of CRLX101, in each case on a once every other week schedule, in combination with 80 mg/m^2 of weekly paclitaxel. The maximum tolerated dose and recommended Phase 2 dose for this combination is 15 mg/m^2 for CRLX101 (every other week) and 80 mg/m^2 for weekly paclitaxel (3 weeks on/1 week off). No dose limiting toxicities were observed.

Partial response and stable disease rates were 56% (5/9), and 11% (1/9), respectively. To date, the only Grade ≥3 treatment-related adverse event was neutropenia, which occurred in two patients (one Grade 3 and one Grade 4). The most common adverse events (> 30%) were fatigue, neutrophil count decreased, and nausea.

"We are rapidly accruing additional patients at the recommended Phase 2 dose," said Adrian Senderowicz, M.D., Senior Vice President and Chief Medical Officer of Cerulean. "These additional patients will deepen our understanding of this combination and supplement our available knowledge of the combination of CRLX101 and Avastin® (bevacizumab) before launching a pivotal study in relapsed ovarian cancer."

In a human ovarian xenograft model, the combination of CRLX101 and paclitaxel was synergistic. In this preclinical study, tumor growth delay and survival were greater for the combination than either treatment alone or the sum of both individual treatments, and the combination appeared to be well tolerated in mice.

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 our 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 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-1α (HIF-1α), 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 and 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 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 1/2a 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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 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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