Cerulean Announces First Patient Dosed in Phase 1b/2a Study of CRLX101 in Combination with Avastin® in Renal Cancer

CAMBRIDGE, Mass. – July 2, 2012 – Cerulean Pharma Inc., a leader in developing dynamically tumor-targeted nanopharmaceuticals, today announced that the first patient has been dosed in a Phase 1b/2a study of its lead product candidate, CRLX101, in combination with Avastin®, in metastatic renal cell carcinoma (mRCC) patients. The company also announced the completion of enrollment of its randomized Phase 2 study in advanced non-small cell lung cancer.

Having completed enrollment of a 150-patient randomized Phase 2 study in advanced non-small cell lung cancer, Cerulean is beginning to capitalize on the breadth of the CRLX101 opportunity by expanding its development into additional tumor types with several studies conducted by leading investigators. This newly opened trial is designed to evaluate the activity of CRLX101, a nanopharmaceutical that inhibits both topoisomerase 1 and hypoxia-inducible factor-1 alpha, in combination with Avastin® in mRCC patients whose disease has progressed following treatment with at least one prior molecularly targeted therapy. This study, which incorporates a rapid dose escalation stage and a subsequent efficacy stage, is being conducted at the Abramson Cancer Center of the University of Pennsylvania and is led by principal investigator Stephen Keefe, M.D.

"We have observed that the unique intratumor pharmacokinetic properties of our nanopharmaceuticals can lead to novel pharmacodynamic effects," said Edward Garmey, M.D., chief medical officer of Cerulean. "We will be collaborating with Dr. Keefe and his colleagues to assess the impact of CRLX101 on HIF-1 alpha, an exciting oncology drug target that appears to be widely upregulated in hypoxic conditions and in RCC."

"Reaching multiple tumor targets at once may be more efficient at shrinking patients' tumors, and make them less likely to become resistant to the drugs. In this new trial for patients with RCC, we will learn if CRLX101 is synergistic with Avastin®, the leading VEGF inhibitor," Dr. Keefe said. "We are excited about the potential efficacy of combining these two agents, which mechanistically reinforce each other. The benefit of this approach—attacking multiple targets at once—is not limited to RCC, however, and could be applicable in other cancers as well."

About CRLX101

CRLX101 is an investigational anti-cancer agent that is a dual inhibitor of topoisomerase 1 and hypoxia-inducible factor-1 alpha. CRLX101 is a dynamically tumor-targeted nanopharmaceutical designed to concentrate in tumors, prolonging drug exposure at the site of action. Significant anti-tumor activity has been observed across a wide range of cancers in animal models. CRLX101 is currently in Phase 2 clinical development. More information on CRLX101 clinical studies can be found at www.clinicaltrials.gov.

About Cerulean Pharma Inc.
Cerulean Pharma Inc. is a clinical-stage company specializing in the development of dynamically tumor-targeted nanopharmaceuticals. Cerulean is applying its proprietary nanopharmaceutical platform to advance a new class of therapeutic agents to address significant unmet medical needs. With an initial focus in oncology, the Company's technology platform can be applied to a wide range of drug molecules, ranging from small molecules to peptides and RNAs. Cerulean is privately financed and funded by experienced healthcare investors, including Polaris Venture Partners, Venrock, Lilly Ventures, Lux Capital, Bessemer Venture Partners, and CVF, LLC. Cerulean is located in Cambridge, Massachusetts. For more information, please visit the Company's website at http://www.ceruleanrx.com.

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