



## **Cerulean Pharma Doses First Patients in Randomized Phase 2 Clinical Study of CRLX101 in Non-Small Cell Lung Cancer**

CAMBRIDGE, Mass. – July 12, 2011 – [Cerulean Pharma Inc.](#), a leader in designing and developing tumor-targeted nanopharmaceuticals, today announced the dosing of the first patients with CRLX101 in a randomized, controlled non-small cell lung cancer (NSCLC) Phase 2 clinical trial.

“The initiation of this Phase 2 study marks a major milestone in the clinical advancement of nanopharmaceuticals,” said Oliver Fetzter, Ph.D., president and chief executive officer of Cerulean. “Cerulean is excited to develop CRLX101 as a potential new therapy for lung cancer patients who otherwise have limited treatment options.”

The primary objective of the Phase 2 study is to assess the efficacy and safety of CRLX101 in advanced NSCLC patients whose disease has progressed following one or two prior regimens of therapy. Approximately 150 patients are anticipated to be enrolled in this study at 26 clinical trial sites in Russia and Ukraine. Patients will be randomized 2:1 to receive either CRLX101 plus best supportive care or best supportive care, respectively. Patients will be evaluated for overall survival, progression-free survival, tumor response, and pharmacokinetic parameters.

“Cerulean is a leading developer of cancer-focused nanopharmaceuticals and I am thrilled to advance this tumor-targeted agent into Phase 2 development,” said Edward Garmey, M.D., chief medical officer of Cerulean. “Based on exciting preclinical and clinical data, CRLX101 has the potential to be effective in both squamous and non-squamous histology patient populations, as well as in patients with a variety of tumor mutational markers including KRAS and EGFR. There may exist, therefore, the opportunity to consolidate rather than further divide the treatment landscape in lung cancer, while improving safety and quality-of-life parameters.”

### **About CRLX101**

CRLX101 is a tumor-targeted nanopharmaceutical containing camptothecin, an inhibitor of both topoisomerase 1 and hypoxia-inducible factor-1 alpha (HIF-1 $\alpha$ ). CRLX101 is designed to concentrate in tumor tissue and tumor cells, prolonging drug exposure at the site of action. CRLX101 has demonstrated significant anti-tumor activity across a wide range of cancers in animal models and has been well tolerated in a recent 36 patient Phase 2a solid tumor clinical trial. CRLX101 is currently in Phase 2 clinical development. More information on CRLX101 clinical studies can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

**About Cerulean Pharma Inc.**

Cerulean Pharma Inc. is a clinical-stage company specializing in the design and development of tumor-targeted nanopharmaceuticals. Cerulean is applying its proprietary nanopharmaceutical platform technologies and specialized capabilities to advance a new class of therapeutic agents for diseases with unmet medical needs. With an initial focus in oncology, the Company's technology platform can be readily 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, Alexandria Real Estate Equities, and William H. Rastetter. Cerulean is located in Cambridge, Massachusetts. For more information, please visit the Company's website at <http://www.ceruleanrx.com>.

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