



Cornerstone Pharmaceuticals, Inc  
1 Duncan Drive  
Cranbury, NJ 08512

Media Contact: Meghan Weber  
Liza Sullivan & Associates  
(917) 399-8713  
news@cornerstonepharma.com

**WAKE FOREST BAPTIST MEDICAL CENTER AND CORNERSTONE PHARMACEUTICALS  
PRESENT INTERIM DATA FROM PHASE I TRIAL OF CPI-613 IN ACUTE MYELOID LEUKEMIA  
Key Findings to be Presented at the annual meeting of the American Society of  
Clinical Oncology (ASCO)**

**CHICAGO, IL, JUNE 3, 2011** – Cornerstone Pharmaceuticals and Wake Forest Baptist Medical Center today announced key findings from a Phase I clinical trial of Cornerstone’s first –in-class cancer metabolism inhibitor drug, CPI-613 in Acute Myeloid Leukemia (AML). Data will be presented at the 47<sup>th</sup> Annual meeting of American Society of Clinical Oncology (ASCO): <http://www.chicago2011.asco.org/> Cornerstone is a leader in the discovery and development of cancer therapies based on the science of cancer metabolism.

CPI-613 is being studied at Wake Forest Baptist’s Comprehensive Cancer Center to evaluate safety, tolerability, maximum tolerated dose, efficacy, and pharmacokinetics for patients with relapsed and refractory hematologic malignancies. The novel agent, CPI-613, has activity against several acute leukemia cell lines and may have activity in patients with relapsed disease. The mode of cytotoxicity and degree of synergy with more traditional agents remains a focus of ongoing study.

“This study is important because relatively few treatment options exist for patients with AML,” said CEO Cornerstone Pharmaceuticals, Robert Shorr, Ph.D. “Preliminary results from the ongoing Phase I study demonstrate the safety of first-in-class agent, CPI-613, with very few adverse events, and support further exploration of CPI-613 as a potential treatment for AML and other hematologic malignancies.”

According to the National Cancer Institute, 1 in 77 men and women will be diagnosed with leukemia during their lifetime. It is estimated that of the 43,050 Americans diagnosed annually, 21,840 of those will die of leukemia in 2011. Chemotherapy is the standard of treatment for untreated adult acute myeloid leukemia (AML). Cornerstone’s CPI-613 may represent a potential new alternative treatment for this disease

“I am very excited at the opportunity to present our data from the lab as well as our ongoing phase I trial at ASCO,” said Timothy S. Pardee, M.D., Ph.D., lead investigator for the study. “CPI-613 is a very intriguing compound and I hope our studies will lead to improved care for patients who suffer hematologic malignancies.”

Pardee will present the data at ASCO June 3-7 in Chicago. The poster session for the study will be on Monday, June 6 from 1 p.m. to 5 p.m. at McCormick Place Hall A. To view the complete abstract



of the study (#6590), visit [http://abstract.asco.org/AbstView\\_102\\_82032.html](http://abstract.asco.org/AbstView_102_82032.html) . More information about clinical trial enrollment is available at <http://www.wakehealth.edu>.

### **About CPI-613**

CPI-613 is the first drug in a new chemical class that, through a novel mechanism, targets metabolic changes considered to be common to many, if not all, cancer types and not present in normal cells. Patients with solid tumors and hematologic cancers are currently being enrolled in multiple Phase I and Phase I/II human clinical trials evaluating CPI-613. These trials include a Phase I/II single agent trial for patients with solid tumors who have failed all other therapy options, a Phase I/II combination trial with gemcitabine in newly diagnosed or relapsed patients, and a single agent trial in hematologic malignancies. CPI-613 was granted orphan drug status by the US FDA for pancreatic cancer, which has a poor prognosis, spreads rapidly and often goes undetected in its early stages. For further information, visit <http://www.cornerstonepharma.com>.

### **About Cornerstone Pharmaceuticals**

Cornerstone Pharmaceuticals, Inc. is a privately held company that is committed to changing the way cancer is treated through the discovery and development of innovative therapies capitalizing on the unique metabolic processes of cancer cells. The company's founding members, management and scientific advisory team include pre-eminent scientists focused on cancer cell metabolism, cancer research and drug development. The company's unique approach to targeting cancer metabolism has led to the discovery of first-in-class drugs with the potential to transform the way cancer is treated. Its lead drug, CPI-613, is currently being evaluated in three ongoing Phase I and Phase I/II clinical trials in a variety of tumor types.

### **About Wake Forest Baptist Medical Center**

Wake Forest Baptist Medical Center ([www.wakehealth.edu](http://www.wakehealth.edu)) is a fully integrated academic medical center located in Winston-Salem, N.C. Wake Forest School of Medicine directs the education and research components, with the medical school ranked among the nation's best and recognized as a leading research center in regenerative medicine, cancer, the neurosciences, aging, addiction and public health sciences. Piedmont Triad Research Park, a division of Wake Forest Baptist, fosters biotechnology innovation in an urban park community. Wake Forest Baptist Health, the clinical enterprise, includes a flagship tertiary care hospital for adults, Brenner Children's Hospital, a network of affiliated community-based hospitals, physician practices and outpatient services. The institution's clinical programs and the medical school are consistently recognized as among the best in the country by *U.S. News & World Report*.

# # #

This release contains forward-looking statements. These statements relate to future events or each company's future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "estimate", "predict", "potential" or "continue", the negative of such terms, or other comparable terminology. These statements are only predictions. Actual events or results may differ materially from those in the forward-looking statements as a result of various important factors.



Although we believe that the expectations reflected in the forward-looking statements are reasonable, such statements should not be regarded as a representation by the company, or any other person, that such forward looking statements will be achieved. The business and operations of the company are subject to substantial risks which increase the uncertainty inherent in forward-looking statements. We undertake no duty to update any of the forward-looking statements, whether as a result of new information, future events or otherwise. In light of the foregoing, readers are cautioned not to place undue reliance on such forward-looking statements.