



Cornerstone Pharmaceuticals, Inc
1 Duncan Drive
Cranbury, NJ 08512

Media Contact: Meghan Weber
Liza Sullivan & Associates
(917) 399-8713

Cornerstone Pharmaceuticals Announces Initiation of Clinical Trials of CPI-613 for the Treatment of Cancer

First-in-class Altered Energy Metabolism-Directed compound targets metabolic changes found in multiple tumor types but not normal cells

Cranbury, NJ, September 24, 2008 - Cornerstone Pharmaceuticals Inc., a privately held pharmaceutical company, announced today that it has begun dosing patients in a recently approved safety and early efficacy clinical trial of CPI-613, its novel first-in-class Altered Energy Metabolism-Directed (AEMD) compound being evaluated for potential use in a wide array of cancers. Health Canada and the US FDA have approved the initiation of studies of CPI-613, which will be conducted at clinical trial sites in both the US and Canada.

“The recent regulatory approvals and commencement of this clinical trial in both the US and Canada represent significant milestones in the global development of the company’s AEMD compound platform. Given the novelty of the proposed mechanism of action and the highly encouraging pre-clinical efficacy and safety data, we look forward to advancing the development of this promising class of agents to therapeutic fruition for patients suffering from many types of cancer,” said Robert J. Rodriguez, President and Chief Operating Officer of Cornerstone.

Recent molecular oncology studies have focused on the significant genetic differences between different types of cancers. However, it has long been recognized that metabolic energy processes in the majority of cancer cells are similar to each other, but quite distinct from that of normal cells. This observation, first made by Nobel Laureate Otto Heinrich Warburg in 1924 (the “Warburg Effect”), forms the basis for recent significant advances in cancer imaging by positron emission tomography (PET). Because this altered energy metabolism is common to many types of cancer but not normal cells, it is also an attractive target for therapeutic development.

CPI-613 and related compounds are well tolerated in several different animal tumor models at doses that significantly exceed the effective anti-tumor doses in these models. These findings, among others, led to the decision to seek regulatory approval to begin clinical trials. The approved trial is designed to be an open label, dose-escalation study to evaluate safety, tolerability, maximum tolerated dose, efficacy, and pharmacokinetics of CPI-613 in multiple types of cancer. Additional information regarding this clinical trial may be found at www.clinicaltrials.gov.

The AEMD technology platform being developed by Cornerstone is based upon the research of Paul M. Bingham, Ph.D. and Zuzana Zachar, Ph.D., Stony Brook University, Stony Brook, NY.



Recently, Cornerstone Pharmaceuticals and Professors Bingham and Zachar were awarded a matching Innovative Technology Development grant from the Center for Biotechnology, a NYSTAR Center for Advanced Technology at Stony Brook University.

"Given the competitive nature of these grants and the extensive peer review required, we are encouraged by the outside expert evaluation and validation of our efforts and the support of the Center for Biotechnology," said Cornerstone CEO Rob Shorr, Ph.D., D.I.C.

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. Cornerstone is the only company that currently has a drug in clinical trials targeting certain key enzymes crucial to cancer cell metabolism. 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. For further information, visit <http://www.cornerstonepharma.com>. Or contact: Meghan Weber at (917) 399-8713.

About Whitehead Institute

Whitehead Institute for Biomedical Research is a leading, nonprofit research and educational institution that has defined the cutting edge of biomedical science, creating a legacy of research excellence and academic eminence since 1982. Wholly independent in its governance, finances and research programs, Whitehead shares a teaching affiliation with Massachusetts Institute of Technology (MIT), offering the intellectual, collegial and scientific benefits of a leading research university.

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