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**FOR IMMEDIATE RELEASE**

**CORNERSTONE PHARMACEUTICALS INITIATES  
PHASE I/II COMBINATION THERAPY CLINICAL TRIAL  
OF CPI-613 FOR TREATMENT OF PANCREATIC  
CANCER**

***First-in-class Altered Energy Metabolism Directed (“AEMD”)  
Compound Targets Metabolic Changes Found In Multiple Tumor  
Types***

**Cranbury, NJ, May 21, 2009** – Cornerstone Pharmaceuticals, Inc., a privately-held pharmaceutical company, announced today that it has begun a phase I/II clinical trial of CPI-613, the initial candidate to emerge from the company’s Altered Energy Metabolism Directed technology platform. The drug will be used in combination with gemcitabine, a standard chemotherapeutic for the treatment of pancreatic and other cancers. Patients newly diagnosed and intended to be treated with gemcitabine may be eligible for this study. This positions CPI-613 for potential “front line” use.

CPI-613 is the first drug in a new chemical class that, through a novel mechanism, targets metabolic changes that may be common to many cancer types. CPI-613 has been granted orphan drug status by the US FDA for pancreatic cancer, a cancer type that typically has a poor prognosis, spreads rapidly and often goes undetected in its early stages.

It is projected that this year there will be more than 42,000 Americans diagnosed with pancreatic cancer and approximately 35,000 deaths associated with pancreatic cancer.

“The initiation of these trials represents a significant advance in Cornerstone’s continued quest to develop innovative treatments for patients suffering from this devastating disease and other cancer types,” remarked Dr. Robert Shorr, Ph.D. D.I.C., Chief Executive Officer for Cornerstone Pharmaceuticals.

“Pancreatic cancer is one of the most challenging cancers to treat, due in part to a dearth of available drugs. We are very excited by this groundbreaking technology’s potential as an efficacious treatment,” commented Avi Retter M.D., an Oncologist with Eastchester Center for Cancer Care.

The open-label trial is currently underway at the Eastchester Center for Cancer Care in New York for patients who have not previously received CPI-613 or gemcitabine. Additional clinical sites will be added.

The combination therapy study marks Cornerstone Pharmaceuticals’ second drug trial. The first, a safety and early efficacy trial of CPI-613 to evaluate its potential use in a wide array of cancers, commenced dosing patients in September 2008 for patients who had failed current therapies. In addition to these trials, the company is exploring specific changes that occur in tumors that may predict outcome and allow for a more personalized approach for cancer treatment.

### **About Pancreatic Cancer**

Pancreatic cancer originates in the tissues of the pancreas, a large organ that secretes digestive enzymes and hormones that regulate the metabolism of sugars, and typically does not produce symptoms in its early stages. Because the pancreas lies horizontally behind the lower part of the stomach, hidden behind other organs, health care providers cannot see or feel extant tumors during routine exams. As a result, the disease is most often diagnosed after it has reached an advanced stage. Pancreatic cancer has recently attracted more attention as high-profile individuals, such as Carnegie Mellon University professor Randy Pausch and actor Patrick Swayze, have publicly dealt with the disease. Pancreatic cancer has a survival rate of less than 5% and is the fourth leading cause of death in the U.S.

### **About Cornerstone Pharmaceuticals**

Cornerstone Pharmaceuticals, Inc. is a privately held pharmaceutical company singularly focused on the discovery and development of innovative cancer therapies that exploit the metabolic pathways that are common to different cancer types but different from normal cells and tissues. This unique approach, i.e. understanding and addressing what is similar to multiple cancer types rather

than the differences between each, offers a significant opportunity to make a profound impact on the clinical treatment of a variety of cancers.

Cornerstone's AEMD technology platform was established on cancer metabolism research performed in the laboratories of Paul M. Bingham, Ph.D. and Zuzana Zachar, Ph.D., at the State University of New York at Stony Brook, Stony Brook, NY.

Cornerstone has offices and laboratory facilities in both Cranbury, NJ. and Stony Brook, NY. For further information, please log onto <http://www.cornerstonepharma.com>.

For further information or to arrange an interview with Cornerstone Pharmaceuticals senior management please call (212) 843-8073 or email [amazur@rubensteinpr.com](mailto:amazur@rubensteinpr.com).

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