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## **CORNERSTONE PHARMACEUTICALS ANNOUNCES APPROVAL to CONDUCT PHASE I/II CLINICAL TRIAL of CPI-613 IN CANCER PATIENTS BY US FDA**

**Cranbury, NJ, July 24, 2008** – Cornerstone Pharmaceuticals, Inc., a privately-held pharmaceutical company, announced today that it has received clearance from the US Food and Drug Administration (FDA) to begin a Phase I/III clinical trial evaluating the safety and early efficacy of its first-in-class Altered Energy Metabolism-Directed (AEMD) compound, CPI-613, in a variety of cancer types.

CPI-613 targets distinctive changes in the energy generating processes associated with the vast majority of solid tumor types, according to preclinical studies. CPI-613 has shown possible utility in multiple preclinical studies conducted using human tumor biopsies from patients bearing lung, colon, pancreatic and breast tumors as well as cancer cell lines resistant to traditional chemotherapeutics.

The approved clinical trial will be open to patients with a variety of tumor types who have failed previous therapies. It will be conducted at a limited number of clinical trial sites in North America.

CPI-613 represents a subclass of compounds from Cornerstone's AEMD platform which the company has named "Thioctans," and which it believes kill cancer cells by an entirely new and highly selective mechanism.

"We are optimistic that this approval will mark the next important step towards establishing these drugs as a safer, more effective way to treat a wide variety of cancer types, which could make a significant difference in the lives of cancer patients everywhere," said Robert Shorr, Ph.D. D.I.C., Chief Executive Officer of Cornerstone. Recent studies in molecular biology have focused on the significant genetic variances 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. The observation, first made by Nobel Laureate Otto Heinrich Warburg in 1924 (the "Warburg Effect"), forms the basis from recent significant advances in cancer imaging by positron emission tomography (PET). This alters energy metabolism, common to many types of cancer but not normal cells, is the target of Cornerstone's unique chemotherapeutic intervention.



CPI-613 has been shown to be well tolerated at doses that significantly exceed effective anti-tumor doses in several different animal models of human tumors. These findings, among others, have led to the decision to evaluate CPI-613 in this clinical trial.

“Considering the proposed novel mechanism of action, the broad spectrum of activity among a variety of tumor types, the observed low toxicity profile, and potential synergy with existing approved cancer therapies – all of which have been demonstrated in our preclinical work – I believe CPI-613 has the potential to represent a significant advancement in chemotherapeutic options for the treatment and management of a broad variety of cancers,” said Richard Lutes, M.D., Cornerstone’s Chief Medical Officer.

The CPI-613 trial is designed as an open label, dose escalation study to evaluate safety, tolerability, maximum tolerated dose, efficacy, and pharmacokinetics of CPI-613 in multiple types of cancer patients.

Cornerstone has been granted Orphan Drug Designation by the US FDA for the use of CPI-613 in the treatment of pancreatic cancer.

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.

Cancer is the second leading cause of death in the US. Excluding basal and squamous cell skin cancers, the American Cancer society predicts that over 1.4 million new cases of cancer and nearly 600,000 cancer related deaths will occur in the US in 2008.

### **About CPI-613**

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. Cornerstone Pharmaceuticals is currently recruiting patients with solid tumors to advance multiple Phase I/II human clinical trials of CPI-613, CPI-613 is being evaluated in a Phase I/II single agent trial for patients who have failed all other therapy as well as in a Phase I/II combination trial with gemcitabine in newly diagnosed or relapsed patients determined to be treated with gemcitabine. Pancreatic cancer, like many solid tumors, typically has a poor prognosis, spreads rapidly and often goes undetected in its early stages. CPI-613 has been granted orphan drug status by the US FDA for pancreatic cancer.

### **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.

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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.