

Cornerstone Pharmaceuticals Announces Approval to Conduct Phase I/II Clinical Trial of CPI-613 in Cancer Patients by US FDA

Cranbury, NJ and Stony Brook, NY: 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/II 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 including 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. 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). This altered 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 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 is currently developing two distinct technology platforms that show strong specificity for cancer cells of multiple types:

- Altered Energy Metabolism-Directed (AEMD) small molecule drugs; and
- Emulsiphan, a cancer-selective nanotechnology-based delivery system

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

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