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Cornerstone Pharmaceuticals Initiates Phase II Clinical Trial of CPI-613 in Patients with Advanced Solid Tumors

CRANBURY, NEW JERSEY (May 23, 2013) – Cornerstone Pharmaceuticals, Inc., (www.cornerstonepharma.com), a leader in the growing field of cancer metabolism-based therapeutics, today announced the initiation of a Phase II clinical trial of CPI-613 for the treatment of patients with advanced or metastatic solid tumors. CPI-613 is the Company’s lead Altered Energy Metabolism Directed (AEMD) drug candidate, which is designed to disrupt the altered energy-production pathways in cancer cells.

The interventional, open-label clinical study is expected to enroll approximately 100 patients, at Eastchester Center for Cancer Care in New York, with advanced or metastatic solid tumors that have failed, or are not eligible for, all available therapies, or have refused further standard therapy. Participating patients will receive CPI-613, as a single agent, intravenously, twice a week for three weeks of a four week treatment cycle. The primary endpoint of the study is to evaluate overall survival, with secondary endpoints assessing progression free survival, overall response rate, and safety.

Dr. King C. Lee, PhD, Vice President of Regulatory and Clinical Affairs at Cornerstone, stated, “The start of this Phase II trial with CPI-613 is a key milestone in Cornerstone’s clinical development, which is the most advanced and comprehensive in the oncology field. This trial will build on the encouraging insights gained from our previous studies, with the ultimate goal of helping clinicians optimize cancer treatment and improve overall survival outcomes in their patients.”

Robert Rodriguez, Cornerstone’s President and Chief Operating Officer, said, “Cancer metabolism is one of the most promising targets in cancer biology today, with Cornerstone’s lead drug candidate, CPI-613, being the most advanced cancer metabolism therapeutic in the clinic. In previous pre-clinical and clinical studies, CPI-613 has consistently demonstrated its ability to disrupt the metabolic and regulatory processes required for cell growth in solid tumor cell lines and in patients with advanced hematological malignancies. We look forward to increasing our knowledge of the safety and efficacy of CPI-613, with the potential of providing cancer patients with a novel, better tolerated therapeutic alternative treatment.”

CPI-613 induces cancer-specific inhibition of pyruvate dehydrogenase (PDH) and alpha ketoglutarate dehydrogenase (KGDH), key mitochondrial enzymes involved in cancer cell metabolism. Disruption of



PDH and KGDH function cuts off the tumor's energy supply and starves the cancer cell, culminating in cell death. CPI-613 is currently being evaluated in Phase I, I/II and II human clinical trials in solid tumors and hematological malignancies.

CPI-613 is the lead drug candidate from Cornerstone's proprietary AEMD platform. The AEMD drug platform disrupts the biochemical alterations in the conversion of glucose to energy that occur in many types of cancer cells. These essential bioenergetic differences are linked to critical pathways, particularly those that support cancer cell growth and development.

About Eastchester Center for Cancer Care

The Eastchester Center for Cancer Care (eastchestercenter.com) is a state-of-the-art comprehensive cancer treatment center located in the Bronx, N.Y., providing unparalleled cancer care for the Bronx, Queens, Westchester, and greater New York. The Center treats patients through an innovative integration of the latest medical technology with a highly caring team of devoted physicians and clinical staff, in an environment designed to foster feelings of warmth and caring to promote the healing process.

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. www.cornerstonepharma.com.

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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.