

Cornerstone Pharmaceuticals, Inc. 1 Duncan Drive Cranbury, NJ 08512 Media Contact: Meghan Weber Liza Sullivan & Associates (917) 399-8713 news@cornerstonepharma.com

## CORNERSTONE PHARMACEUTICALS PUBLISHES POSITIVE PRE-CLINICAL STUDY RESULTS COMPARING ITS PROPRIETARY DRUG EMPAC™ TO TAXOL®IN THE JOURNAL OF NANOSCIENCE AND NANOTECHNOLOGY

Findings Show EmPAC™ More Effective Than Taxol®Plus Better Safety Profile

Lee K, Maturo C, Rodriguez R, Nyugen H-L, Shorr R. Nanomedicine - Nanoemulson Formulation Improves Safety and Efficacy of the Anti-Cancer Drug Paclitaxel According to Preclinical Assessment. J. Nanosci. Nanotechnol. 11:1\infty15, 2011

## **CRANBURY, NJ, September 15, 2011** – Cornerstone Pharmaceuticals, Inc.,

(http://www.cornerstonepharma.com), a leader in cancer metabolism-based therapeutics, today announced the publication of data from preclinical studies on EmPAC™, its nanoparticle reformulation of paclitaxel, in the August issue of the Journal of Nanoscience and Nanotechnology. (http://bit.ly/nLtR5v) The publication highlights data demonstrating improved safety and efficacy of EmPAC™ versus Taxol®, the generic formulation of paclitaxel and one of the most widely prescribed chemotherapies. EmPAC™ is a nanoemulsion formulation of Paclitaxel and is the lead product candidate of Cornerstone's proprietary Emulsiphan™ cancer selective delivery nanotechnology platform. Taxol®, an injectable formulation of Paclitaxel, is currently used to treat a variety of cancers, including ovarian carcinomas, breast cancer, non-small cell lung cancer, and AIDS-related Kaposi's sarcoma.

The objectives of the preclinical work were to assess and compare the safety and efficacy of  $EmPAC^{TM}$  versus Taxol®.

In several preclinical studies, including non-small cell lung cancer and a melanoma xenograft model, EmPAC™ demonstrated greater tumor growth inhibition compared to Taxol® at comparable doses. Improved efficacy is believed to be related to the ability of the Emulsiphan nanoparticle technology to induce greater uptake of Paclitaxel into tumors at cellular levels, which was demonstrated in both radio labeled as well as antibody based assays.

In animal toxicology studies, EmPAC™ demonstrated greater safety compared to Taxol®. EmPAC™ does not contain any of the ingredients used in formulating paclitaxel – the active ingredient in Taxol®, such as polyethylated or polyoxyl castor oil, which are reported to have related toxicities.

"The study results published in The Journal of Nanoscience and Nanotechnology further validate the potential of Emulsiphan as a safe and efficacy enhancing drug delivery solution for anticancer agents," said Dr. Robert Shorr, CEO of Cornerstone Pharmaceuticals, Inc.



"Combining anticancer agents with a targeted drug delivery technology, such as Emulsiphan, could greatly improve patient outcomes by delivering more drug to where it's needed, thereby reducing harmful side effects."

"The results described in this paper suggest that Emulsiphan technology has the potential to improve the safety and efficacy of not only FDA-approved anticancer drugs, but also novel anticancer drugs that are currently under clinical development," said Dr. King Lee, VP of Clinical and Regulatory Affairs of Cornerstone Pharmaceuticals, Inc.

Cornerstone's Emulsiphan nanoemulsion-based drug delivery system is a novel drug-delivery technology that is believed to deposit cancer-fighting drugs directly into cancer cells—not just the tumor mass—by leveraging the distinct metabolism of these cells. Just as the body needs nutrients to survive, cancer cells depend on certain nutrients to make energy and to proliferate. The Company believes Emulsiphan contains nutrients that are attractive primarily to tumors and therefore selectively taken up by them.

Emulsiphan is designed to maximize drug concentration into tumor cells thereby enhancing the anti-cancer compound's selectivity and specificity, leading to a potentially safer and more effective cancer treatment. This is of particular importance and potential for those tumors that may be located in a site not otherwise amenable to surgical interventions.

Many approved drugs as well as newer cancer selective agents in use or in development today are difficult to solubilize and rely on diffusion after intravenous or oral administration to reach tumor cells. Often drugs may be metabolized and cleared from the body prior to reaching their target and as cells are distal from a tumor's vasculature; it is more difficult for a drug to reach a sufficient concentration to be useful. While technology continues to be evaluated for increasing the concentration of drugs in a tumor mass, some of these may actually inhibit the uptake of a drug into tumor cells. Cornerstone's Emulsiphan drug delivery technology aims to overcome these challenges so that increasing the required effective dose doesn't deliver treatment at the expense of risking a patient's safety.

## **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. http://www.cornerstonepharma.com



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.