

## **China Pharma Holdings, Inc. Successfully Completes Phase I Clinical Trials of New Anti-Drug-Resistance Antibiotic**

-- Novel combination of 3rd generation cephalosporin and beta-lactamase inhibitor moves one step closer to China's large cephalosporin antibiotic market --

HAIKOU CITY, China, Sept. 22 /PRNewswire-Asia-FirstCall/ -- China Pharma Holdings, Inc. ("China Pharma") (NYSE Amex: CPHI), which develops, manufactures, and markets specialty pharmaceutical products in China, today announced that the Company has successfully completed Phase I clinical trials of its novel cephalosporin-based combination antibiotic.

Cephalosporin continues to be the most widely prescribed class of antibiotics in China. According to the SFDA, approximately 50% of antibiotic sales are derived from cephalosporin. Sales of cephalosporin antibiotics were estimated to be over \$6 billion in 2009, and are projected to be \$7.5 billion in 2010, \$11 billion in 2012, and \$17.4 billion in 2015<sup>[1]</sup>. Due to broad usage of antibiotics, including cephalosporin, drug resistance has become a significant issue in China. The Company believes its new combination antibiotic possesses substantial competitive advantages in this environment, and believes the market opportunity for this drug can reach \$50 million within three years of product launch. The SFDA has designated the Company's combination antibiotic as a Class 1 drug, which carries five-year exclusivity when approved.

The Company's anti-drug-resistance antibiotic, which combines a 3rd generation cephalosporin and a beta-lactamase inhibitor, is expected to be indicated for a wide variety of infections throughout the body, including: upper and lower respiratory tract infections (especially for pneumonia and bronchitis), ear and nose infections, bacterial Septicemia, meningitis, skin and skin structure infections, bone and joint infections, abdominal infections (peritonitis, cholecystitis, etc.), upper and lower urinary tract infections, gonorrhea, and genital infections.

Greater prevalence of drug-resistant extended-spectrum beta-lactamase (ESBL) producing bacteria, such as the enterobacteriaceae family, has prompted numerous in vivo and in vitro studies of the efficacy of this combination. The combination has demonstrated 94.6% efficacy against bacteria strains resistant to the cephalosporin component alone<sup>[2]</sup>. Beyond this clear benefit, the combination exhibits greater spectrum of activity against microorganisms like anaerobic bacteria and pseudomonas, which are not susceptible to the cephalosporin component alone.

Phase I of the clinical trials focused on the study of clinical pharmacology as well as evaluation of safety on the human body, through observing tolerance and pharmacokinetics to provide support for dosage and drug delivery design. Subjects enrolled in the Company's Phase I clinical trials were administered medicine in dosages that varied depending on their



## **China Pharma Holdings, Inc.**

assigned subject groups. The drug tolerance trials included both single tolerance trials and multiple tolerance trials.

"We are very pleased to announce the successful completion of Phase I clinical trials of our new drug candidate with excellent results," commented China Pharma's CEO and President, Ms Zhilin Li. "Our novel combination drug addresses growing resistance to cephalosporin. One of the two primary ingredients in our combination product has been placed on the government's essential drug list, boosting its overall usage in basic level hospitals, which may exacerbate resistance issues in the coming few years and provide an even greater opportunity for China Pharma. Both ingredients in our compound already have demonstrated their efficacy in stand alone form, so we are very optimistic about continued success in the clinical trials setting. We believe that our anti-drug-resistance antibiotic will provide a better therapeutic solution for hospitals, and will generate positive excitement among physicians and hospital professionals upon launch, especially given the limited number of new antibiotic compounds and new combination antibiotics coming to market."

### **About China Pharma Holdings, Inc.**

China Pharma Holdings, Inc. is a specialty pharmaceutical company with rapidly growing profit that develops, manufactures, and markets treatments for a wide range of high incidence and high mortality conditions in China, including cardiovascular, CNS, infectious, and digestive diseases. The Company's cost-effective, high margin business model is driven by market demand and supported by eight scalable GMP-certified product lines covering the major dosage forms. In addition, the Company has a broad and expanding distribution network across 30 provinces, municipalities and autonomous regions. The Company is registered in Delaware, USA. Hainan Helpson Medical & Biotechnology Co., Ltd. (Helpson), located in Haikou City, Hainan Province, China, is a wholly owned subsidiary of China Pharma Holdings, Inc. For more information about China Pharma Holdings, Inc., please visit <http://www.chinapharmaholdings.com>.

### **Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995**

Certain statements in this press release constitute forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Any statements set forth above that are not historical facts are forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements, which may include, but are not limited to, such factors as success of new product development, unanticipated changes in product demand, increased competition, downturns in the Chinese economy, uncompetitive levels of research and development, and other information detailed from time to time in the Company's filings and future filings with the United States Securities and Exchange Commission. The forward-looking statements made herein speak only as of the date of this press release and the Company undertakes no duty to update any forward-looking statement to conform the statement to actual results or changes in the company's expectations.



**China Pharma Holdings, Inc.**

<sup>[1]</sup> MENET, SFDA, and InterFax-China News Agency "China – Pharmaceuticals & Health Technologies Weekly" Volume VI, Issue 29

<sup>[2]</sup> The Internet Journal of Infectious Diseases 2009: Volume 7 Number 2

