



## **Spectrum Pharmaceuticals Investigational New Drug Application for SPI-1620 Cleared by U.S. Food & Drug Administration**

### **- Phase 1 Dose-Escalation Study to Begin Recruiting Patients Shortly**

IRVINE, Calif., Aug 09, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Spectrum Pharmaceuticals, Inc., (Nasdaq: SPPI) today announced that the FDA has cleared the Investigational New Drug (IND) application for the use of SPI-1620 in patients with recurrent or progressive carcinoma. SPI-1620 is being developed as an adjunct to chemotherapy. SPI-1620 is a highly selective endothelin-B agonist that has demonstrated in experimental animal models a transient and selective increase in blood flow to tumors by over 300% and an increased delivery of anticancer drugs to the tumor while essentially sparing normal tissues and organs, thereby increasing the efficacy and the therapeutic index of these drugs.

"We are pleased that the FDA has cleared the IND for SPI-1620," said Rajesh C. Shrotriya, M.D., President and Chief Executive Officer of Spectrum Pharmaceuticals, Inc. "SPI-1620 has shown preclinical evidence of increasing a cancer tumor's uptake of doxorubicin and other anti-cancer agents. We believe SPI-1620 could have a broad range of applications as an adjunct to chemotherapy in the treatment of solid tumors."

The Phase 1 trial is an open label, dose-escalation study assessing the safety, tolerability, pharmacokinetics and pharmacodynamics in patients with recurrent or progressive carcinoma. The trial is expected to begin enrolling patients once the Investigational Review Boards approve the study.

#### About SPI-1620

The American Cancer Society estimates there will be more than 1.4 million new cases of cancer in the U.S. in 2007. Chemotherapy is one of the mainstays of therapy for solid tumors. However, chemotherapy often fails because adequate tissue levels of the cytotoxic agents are not achieved in the tumor and serious side effects result from toxicity to normal cells. Spectrum Pharmaceuticals is developing a novel approach that takes advantage of endothelin biology and the unique angioarchitecture of tumor blood vessels to overcome these problems.

In animal models, SPI-1620 causes a selective and transient increase in blood flow to tumors. Increased blood flow in turn led to an increase in drug delivery to tumors, which in turn enhanced the efficacy of the chemotherapeutic drugs. Proof-of-principle studies have been done in several tumor models, such as breast and prostate tumor models in rats, and melanoma and ovarian tumor models in mice. An increase in the delivery to tumors of different chemotherapeutic drugs such as paclitaxel, cisplatin, doxorubicin, cyclophosphamide, and 5-FU has been shown in animal models. Furthermore, SPI-1620 enhanced the efficacy of chemotherapeutic drugs as demonstrated by improved efficacy of paclitaxel against breast tumor models and improved efficacy of cisplatin and cyclophosphamide against ovarian tumor models. Similarly SPI-1620 improved the efficacy of doxorubicin and 5-FU in prostate tumor models.

Spectrum has proprietary worldwide rights to SPI-1620.

#### About Spectrum Pharmaceuticals

Spectrum Pharmaceuticals acquires, develops and commercializes a diversified portfolio of oncology drug candidates that meet critical health challenges for which there are few other treatment options. The company's pipeline includes promising early and late-stage drug candidates with unique formulations and mechanisms of action that address the needs of seriously ill patients, such as at-home chemotherapy and new treatment regimens for refractory disease. For more information, please visit our website at <http://www.spectrumpharm.com>.

Forward-looking statements -- This press release may contain forward- looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements include but are not limited to statements that relate to our business and its future, Spectrum's ability to identify, acquire, develop and commercialize its portfolio of drug candidates, the Company's promising pipeline, the safety and efficacy of SPI- 1620, that SPI-1620 could have a broad range of applications as an adjunct to chemotherapy in the treatment of solid tumors, the initiation of a Phase 1 trial and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that our existing and new drug candidates, may not prove safe or effective, the possibility that our existing and new drug candidates may not receive approval from the FDA, and other regulatory agencies in a timely

manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that preclinical results will not be indicative of clinical results, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our lack of revenues, our limited marketing experience, our dependence on third parties for clinical trials, manufacturing, distribution and quality control and other risks that are described in further detail in the Company's reports filed with the Securities and Exchange Commission. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law.

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