



**Charleston Laboratories, Inc. Attends Pre-IND Meeting**

***Charleston completes successful Type B, Pre-IND meeting with FDA's Division of Anesthesia, Analgesia and Rheumatology Products on November 8, 2007, held at FDA's Silver Spring, Maryland offices.***

**Charleston, South Carolina** – November 8, 2007 – Charleston Laboratories, Inc, an emerging specialty pharmaceutical company dedicated to reducing opioid induced nausea and vomiting (OINV) in opioid pharmaceuticals, publicly announced today the results of its Pre-IND meeting with FDA on its first drug candidate. At this meeting Charleston received approval to proceed with its proposed Clinical Development Program, utilizing a modified 505 (b)(2) NDA process.

Commenting on this meeting with the FDA, Mr. John Ameling, Vice President, Regulatory Affairs, at Charleston Laboratories, noted that "the Agency accepted the plan to develop low-dose, immediate-release promethazine, hydrocodone, and acetaminophen, CL-108, which will be indicated for the treatment of moderate-to-severe acute pain and the prevention/reduction of opioid-induced nausea and vomiting (OINV), a new drug indication."



According to Dr. Bernard Schachtel, Charleston Laboratories' Chief Medical Officer, "the Division was forthcoming and helpful, providing guidance to us in defining the clinical development program and the studies planned for it. As a result of this positive interaction," he said, "after we have 'the best' drug formulated, we will feel very comfortable presenting the Agency with an IND Application to review, including a detailed description of the first-in-man study."

All clinical studies for Charleston Laboratories are being overseen by SRC, Inc., a contract research organization based in Jupiter, Florida that is renowned for its clinical trials on patients' symptoms (such as nausea and vomiting) and its record of drug approvals by regulatory authorities in the U.S. and worldwide.

**About Charleston Laboratories, Inc.**

Charleston Laboratories Inc, out of Charleston, SC, is a privately funded specialty pharmaceutical company specializing in the development and commercialization of opioid drugs with minimal or no opioid-induced nausea and vomiting (OINV). Charleston Laboratories intends to enter into both discovery and commercialization alliances with partners motivated to introduce novel pain therapies that eliminate or significantly reduce nausea and vomiting.

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