

## **Strong Efficacy Data Prompt Charleston Laboratories to Halt Phase 3 Study of CL-108 in Patients with Moderate to Severe Acute Pain**

*Study Demonstrates High Statistical Significance in Both Primary Endpoints of Reduction of Opioid-Induced Nausea/Vomiting and Pain*

October 29, 2013 (Jupiter, Florida) – Charleston Laboratories, Inc, an emerging specialty pharmaceutical company focused on the research and development of novel pain products, announced today that it has completed its Phase 3 clinical trial of CL-108 at the midway point. (CL-108 is a strong pain-reliever designed to also prevent nausea and vomiting.) An independent Data Monitoring Committee reviewed the safety and efficacy results in an interim analysis and notified Charleston Labs that the study should be stopped because both efficacy endpoints of the study have been met. The recommendation was based on the demonstration of the safety of CL-108, the significant ( $P < .01$ ) effect on opioid-induced nausea and vomiting (OINV) compared to a commercial product, and the significant ( $P < .01$ ) relief of moderate to severe pain. The Company anticipates filing a new drug application with the FDA upon finalization of clinical studies in the coming year.

“This recommendation by the Data Monitoring Committee is a welcome outcome for Charleston Labs and for patients with acute moderate to severe pain,” said Dr. Bernard Schachtel, Chief Scientific Officer of Charleston Labs. “The early completion of this Phase 3 trial allows us to advance the development of CL-108, which combines an anti-emetic medication with an opioid analgesic for improved treatment of patients with acute moderate to severe pain. The study results also represent confirmation of our pipeline and our research objective, to investigate and develop safe, effective analgesic medications without the side effects of nausea and vomiting.”

“Nausea and vomiting are the most common and untoward side effects of opioid medications and have a significant impact on patients’ lives and the physicians treating these patients,” said Dr. Tong-Joo Gan, Vice Chair, Department of Anesthesiology, Duke University Medical Center. “CL-108 has the potential to greatly reduce this burden on patients, while also streamlining the drug regimen they require. This can enhance patient adherence and improve outcomes for patients suffering acute moderate to severe pain.”

Hydrocodone is the most widely prescribed medication in the United States, with over 131 million prescriptions annually, but up to 60% of patients suffer side effects of nausea and vomiting, causing a significant burden for patients and prescribers, as well

as contributing significant costs to the healthcare system. CL-108 is a novel analgesic, combining 12.5 mg of immediate-release promethazine with 7.5 mg of hydrocodone and 325 mg of acetaminophen. CL-108 is indicated for patients who suffer from moderate to severe acute pain, such as post-operative pain, while significantly reducing or eliminating opioid-induced nausea and vomiting (OINV).

"This is a landmark day for the Charleston team and our shareholders in our quest to develop novel first-in-class pain medications for the millions of patients around the globe who have poorly controlled pain regimens due to opioid or post-operative induced nausea & vomiting. We want to thank all the sites, clinical investigators, study nurses and coordinators, and other staff involved in this trial for their consistent effort in executing a uniquely differentiated study protocol designed by Dr. Schachtel," said Mr. Paul Bosse, President and Chief Executive Officer of Charleston Laboratories. "Nausea and vomiting cannot be managed with over-the-counter medications, requiring patients to return to their healthcare providers urgently seeking a second prescription for an anti-emetic." Mr. Bosse stressed, "At that point, the patient has already experienced poor pain control while trying to deal with nausea and vomiting. CL-108 was designed to provide doctors with a medication that prevents nausea and vomiting, so they can be proactive in their treatment of pain."

## About Charleston Laboratories, Inc.

Charleston Laboratories, Inc is a privately held, specialty pharmaceutical company focused on the research and development of novel pain products that prevent or significantly reduce nausea and vomiting, the two most burdensome side effects related to opioid analgesics and other pain associated disease states. Charleston's product pipeline will address Opioid-Induced Nausea and Vomiting (OINV), Postoperative Nausea and Vomiting (PONV), Chemotherapy-Induced Nausea and Vomiting (CINV), Radiation-Induced Nausea and Vomiting (RINV), and Migraine-Induced Nausea and Vomiting (MINV).

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