



## **PRESS RELEASE**

### **FDA Grants Charleston Laboratories, Inc. Request for Pre-IND Meeting on New Migraine Treatment**

**Charleston, South Carolina** – April 16, 2013 – Charleston Laboratories, Inc, an emerging specialty pharmaceutical company focused on the research and development of novel pain products that prevent or significantly reduce nausea and vomiting related to opioid analgesics and other pain associated disease states, announced today the U.S Food and Drug Administration has granted its request for a Pre-IND meeting to discuss the proposed Investigational New Drug, CL-H1T, as a novel treatment for patients who suffer from migraine pain and migraine induced nausea or vomiting.

“Charleston is very pleased with the positive and prompt response from the Neurology Products Division at FDA” said Mr. John Ameling, Vice President of Regulatory Affairs at Charleston. “This meeting is a positive step towards the development of our novel migraine product, CL-H1T. We look forward to discussing our proposed drug development program with FDA and initiating our clinical trials towards an approvable New Drug Application (NDA).”

“Our meeting with the agency in July is an important step in our development of CL-H1T,” said Mr. Ryan Baker, Executive Vice President and Chief Operating Officer at Charleston Labs. “After our meeting with FDA, we will be looking to enter into the best strategic partnership to successfully complete the clinical trials and support commercialization for CL-H1T to help the millions of patients suffering from migraine headaches and migraine induced nausea or vomiting.”

“This milestone marks the second investigational drug in Charleston’s pipeline to reach the clinic,” Mr. Paul Bosse, President and Chief Executive Officer, commented. “In addition to CL-108, which is in Phase 3 development for the treatment of acute moderate to severe pain, the development of this migraine drug signals our company’s range of pharmaceuticals for different types of pain associated with nausea and vomiting.”

#### **About Charleston Laboratories, Inc.**

Charleston Laboratories, Inc is a 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 new products 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). In addition, Charleston is developing other products without acetaminophen to reduce the potential for liver injury and formulations with abuse deterrent technologies designed to curb misuse and abuse. Charleston Laboratories intends to enter into discovery and commercialization alliances with partners motivated to introduce novel pain therapies that eliminate or significantly reduce nausea and vomiting.

[www.charlestonlabs.com](http://www.charlestonlabs.com).