



## **Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. Announce Three Poster Presentations at American Pain Society Annual Meeting**

**Jupiter, Florida, and Parsippany, NJ** – May 13, 2015 – Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. today announced three poster presentations highlighting additional analyses of data from a pivotal phase 3 clinical trial of the investigational drug CL-108 to be presented at the 34<sup>th</sup> Annual Scientific Meeting of the American Pain Society in Palm Springs, California.

CL-108 is a novel therapy containing a low dose of 12.5 mg immediate-release promethazine with 7.5 mg hydrocodone and 325 mg acetaminophen currently being evaluated in phase 3 studies as a treatment for moderate to severe pain while reducing or preventing opioid-induced nausea and vomiting (OINV). CL-108 uses an innovative formulation to ensure delivery of promethazine, an anti-emetic therapy, prior to the onset of the pain-relieving properties of hydrocodone and acetaminophen to help prevent nausea and vomiting, two common and distressing side effects of opioid treatment.

“Opioid-induced nausea and vomiting, or OINV, represents a significant challenge for patients and physicians alike, complicating pain management,” said Bernard Schachtel, M.D., Chief Scientific Officer at Charleston Laboratories, Inc. “We are eager to develop new patient-oriented methods and measurement tools in our efforts to improve the evaluation, understanding, and treatment of pain.”

“Our goal is to provide physicians and patients with effective and safe therapies that reduce pain without the added burden of unwanted side effects such as nausea and vomiting,” said Mark T. Marino, M.D., Vice President, Clinical Development at Daiichi Sankyo Pharma Development. “We are excited by the data being presented because it underscores our dedication to helping improve the lives of patients who require the short-term use of pain medication.”

### ***Poster #417: OINV in Patients Without Immediate Post-Operative Nausea/Vomiting***

In this subgroup analysis from a pivotal, randomized, double-blind, placebo-controlled, multi-dose Phase 3 study of CL-108 in oral surgery patients, the incidence of OINV in patients without immediate post-operative nausea and vomiting and the prophylactic anti-emetic effect of CL-108 compared to 7.5 mg hydrocodone/325 mg acetaminophen were evaluated. These data will be presented by Elliott Hersh, DMD, MS, PhD, University of Pennsylvania School of Dental Medicine on Thursday, May 14 from 9:30 to 11 am.

### ***Poster #161: Likelihood of OINV in Patients with a History that is Only Suggestive of OINV***

This analysis sought to determine the occurrence and severity of OINV in patients without a clear-cut history of OINV through the use of a Nausea-Prone Questionnaire (NPQ) to identify evidence of previous OINV or other conditions that might predispose patients to nausea and/or vomiting. These data will also be presented by Elliott Hersh, DMD, MS, PhD, University of Pennsylvania School of Dental Medicine on Thursday, May 14 from 9:30 to 11 am.

**Poster #126: Affective and Sensory Qualities of Pain Complement Evaluative Measures of Opioid Analgesia: Results from the Qualities of Dental Pain Index (QDPI)**

This presentation reports on the first use of the Qualities of Dental Pain Index (QDPI), a newly designed research instrument that includes sensory and affective pain measurements to detect and demonstrate the efficacy of a single dose of an approved analgesic (7.5 mg hydrocodone/325 mg acetaminophen). These data will be presented by Bernard Schachtel, MD, Charleston Laboratories on Thursday, May 14 from 3:45 to 5:15 pm.

“The data being presented at APS demonstrate Charleston Laboratories’ commitment to patients, new approaches to research and an enhanced understanding of OINV,” said Paul Bosse, President and Chief Executive Officer of Charleston Laboratories. “We are dedicated to improving the lives of those suffering from the burdensome effects of OINV.”

**About Charleston Laboratories, Inc.**

Charleston Laboratories, Inc. is a privately held, specialty pharmaceutical company focused on the research and development of novel pain products to prevent the burdensome side effects related to opioid analgesics and other products. The Company has a strategic collaboration with Daiichi Sankyo, Inc. for the development and U.S. commercialization of Charleston Laboratories' novel hydrocodone products, including CL-108, which is being developed for the treatment of moderate to severe pain and the prevention of Opioid-Induced Nausea and Vomiting (OINV), two common side effects of opioid therapy.

Charleston's product pipeline currently seeks to address unmet needs in 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). Charleston Laboratories intends to enter into other discovery and commercialization alliances with partners motivated to introduce novel pain therapies that reduce the burdensome side effects related to opioid analgesics and other products. For more information, please visit [www.charlestonlabs.com](http://www.charlestonlabs.com).

**About Daiichi Sankyo**

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, dyslipidemia and bacterial infections used by patients around the world, the Group has also launched treatments for thrombotic disorders and is building new product franchises. Furthermore, Daiichi Sankyo research and development is focused on bringing forth novel therapies in oncology and cardiovascular-metabolic diseases, including biologics. The Daiichi Sankyo Group has created a "Hybrid Business Model," to respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com). Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit [www.dsi.com](http://www.dsi.com).

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