



Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. Initiate Two Phase 3 Clinical Trials on Charleston's Lead Product, CL-108

Jupiter, Florida, and Parsippany, NJ – November 20, 2014 – Charleston Laboratories, Inc., an emerging specialty pharmaceutical company focused on the research and development of novel pain products, and their co-development and co-commercialization partner, Daiichi Sankyo, Inc., initiated two Phase 3 clinical trials on CL-108, Charleston Laboratories' lead product in development. CL-108 is a novel, bi-layered tablet containing 7.5 mg of hydrocodone and 325 mg of acetaminophen with 12.5 mg of immediate-release promethazine.

The studies will evaluate the safety and efficacy of CL-108, the first of its kind intended to treat moderate to severe acute pain while reducing nausea and vomiting, common side effects of opioids. One study is a randomized, double-blind, placebo- and active-controlled trial conducted in patients following bunionectomy surgery at 3 major research centers in the United States. The second study is being conducted at 17 research centers across the country in patients suffering moderate to severe acute pain from osteoarthritis of the knee or hip.

"Following the announcement of our collaboration with Daiichi Sankyo, the initiation of these two clinical trials marks a critical moment in our timeline for Charleston Laboratories," said Mr. Paul Bosse, President and CEO at Charleston Laboratories. "As a result of the planning and hard work by our Chief Scientific Officer, Dr. Bernard Schachtel, and his dedicated research staff, Charleston is already conducting the final studies to support the NDA for CL-108, which is targeted for filing with the FDA later next year."

The results of the first Phase 3 trial were published in abstract form ("Demonstration of the safety and efficacy of CL-108 for moderate-to-severe pain with reduction of opioid-induced nausea and vomiting") in the April 2014 issue of the *Journal of Pain*, the official journal of the American Pain Society.¹ The study was terminated early by an external Data Safety Monitoring Board because of the significant ($p < 0.01$) evidence of the safety and efficacy of CL-108.

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 significantly reduce the burdensome side effects related to opioid analgesics and other products. The Company

recently announced a strategic collaboration for the development and U.S. commercialization of Charleston Laboratories' novel hydrocodone combination products, including CL-108, being studied for the treatment of moderate to severe acute pain as well as the reduction of Opioid-Induced Nausea and Vomiting (OINV).

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.

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. 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.

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ⁱ B Schachtel, N Younes, J Zhou, E Schachtel, E Hersh. Demonstration of the safety and efficacy of CL-108 for moderate-to-severe pain with reduction of opioid-induced nausea and vomiting. *Journal of Pain*. Poster presented at American Pain Society, April 30 to May 3, 2014; Tampa, Florida.