Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. Announce Phase 3 Study of CL-108 Met Primary Endpoints

Jupiter, FL, and Parsippany, NJ –October 29, 2015 – Charleston Laboratories, Inc., and Daiichi Sankyo, Inc., today announced that a third Phase 3 clinical trial of CL-108, an opioid-containing formulation, met its primary endpoints. CL-108 is a bi-layered tablet containing 7.5 mg of hydrocodone and 325 mg of acetaminophen uniquely formulated with 12.5 mg of rapid-release promethazine. This novel formulation is being developed as a treatment for moderate to severe pain and the prevention of opioid-induced nausea and vomiting (OINV).

This recently completed Phase 3 clinical trial was a randomized, double-blind, placebo- and active-controlled study in over 550 patients in the U.S. who experienced moderate to severe pain after bunionectomy surgery (removal of bunions from the foot). Results from the study demonstrated significant pain relief and prevention of OINV by CL-108 (both $p<0.001$).

"Meeting the primary endpoints of this pivotal phase 3 study marks an important milestone in the development of CL-108 as a potential treatment option for patients with moderate to severe pain while preventing opioid-induced nausea and vomiting," said Bernard Schachtel, M.D., Chief Scientific Officer at Charleston Laboratories, Inc.

"OINV is a condition that can affect a patient's ability to achieve effective pain control," said Mark T. Marino, M.D., Vice President, Clinical Development at Daiichi Sankyo, Inc. "Daiichi Sankyo is committed to developing medicines, such as CL-108 that address unmet patient needs for pain management."

Mr. Paul Bosse, President and Chief Executive Officer at Charleston Laboratories, Inc., said: "This major milestone marks a critical step forward in the development of CL-108 and the joint Charleston Laboratories and Daiichi Sankyo clinical research program. We look forward to providing the full results of this study, as well as additional reports on CL-108 in the near future, as we prepare to submit a New Drug Application (NDA) for U.S. FDA review."

"The synergy between Charleston Laboratories and Daiichi Sankyo has enabled great progress in the development of CL-108," said Ken Keller, President, U.S. Commercial of Daiichi Sankyo, Inc. "If approved, CL-108 represents an opportunity to deliver on our commitment to bring important new therapies to patients and to continue to build the Daiichi Sankyo U.S. portfolio of medicines in the area of pain management."

Further analysis of the study results is ongoing and the results will be submitted to an upcoming medical conference and peer-reviewed publication.

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 the burdensome side effects related to opioid analgesics and other products. The Company recently announced a strategic collaboration with Daiichi Sankyo, Inc. 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 pain as well as the prevention of Opioid-Induced Nausea and Vomiting (OINV).

Charleston's product pipeline currently seeks to address unmet medical needs for patients with 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 prevent 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 diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 17,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to its strong portfolio of medicines for hypertension, dyslipidemia, bacterial infections, and thrombotic disorders, the Group's research and development is focused on bringing forth novel therapies in cardiovascular-metabolic diseases, pain management, and oncology, including biologics. 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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