Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. Announce FDA Acceptance of New Drug Application (NDA) for CL-108

Jupiter, Florida, and Parsippany, NJ – June 13, 2016 – Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for CL-108 for the relief of moderate to severe pain while preventing or reducing the associated opioid-induced nausea and vomiting (OINV). CL-108 is a fixed-dose, immediate-release bi-layered tablet with a rapid release layer containing 12.5 mg of promethazine and a second layer containing 7.5 mg of hydrocodone and 325 mg of acetaminophen. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of January 31, 2017.

"With this NDA acceptance, patients are one step closer to being able to have an option for relieving pain while also preventing or minimizing the nausea and vomiting side effects of opioid treatment," said Paul Bosse, President and Chief Executive Officer of Charleston Laboratories, Inc. "At Charleston Laboratories, a key part of our mission is to develop and commercialize products that provide patients with novel solutions for improving their pain management. This acceptance represents an important contractual milestone under our relationship with Daiichi Sankyo. "

"Daiichi Sankyo is dedicated to bringing innovative medicines to patients with unmet medical needs in the area of pain management," said Mahmoud Ghazzi, MD, PhD, President and Global Head of Development for Daiichi Sankyo. "We look forward to working closely with the FDA during the review process for CL-108 and support the Agency's efforts to foster the safe and responsible use of opioid medications."

The NDA for CL-108 is supported by two pivotal randomized, double-blind, placebo- and active-controlled Phase 3 clinical studies, one following oral surgery (molar removal) and the other after bunionectomy surgery (removal of bunions from the foot), as well as by an additional Phase 3 open-label, actual use safety study in patients with moderate-to-severe acute pain, or "flares," associated with osteoarthritis of the knee or hip. More than 1,000 patients have been enrolled in the CL-108 Phase 3 clinical trial program. A human abuse liability study has also been conducted.

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 studied for the treatment of moderate to severe pain while preventing or reducing the associated 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 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 16,000 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 a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. To learn more about Daiichi Sankyo, Inc., please visit www.dsi.com.

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