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Singapore: New Jersey's Charleston Laboratories Inc and Japanese major Daiichi Sankyo Inc have announced that the US 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, 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.