



Charleston Laboratories, Inc. Reacquires Rights to Novel Investigational Treatment CL-108, for Acute Pain and Opioid-Induced Nausea and Vomiting

Jupiter, Florida – August 31, 2017 – Charleston Laboratories, Inc., announced that it has reacquired all US rights to develop and commercialize its hydrocodone pipeline products from Daiichi Sankyo Co., Ltd. and its US subsidiary, Daiichi Sankyo, Inc. This ends a three-year collaboration between the companies; Charleston Laboratories is now centralizing its comprehensive acute pain portfolio and accelerating the process to bring CL-108 to market.

“We thank Daiichi Sankyo for their partnership, and now with a singular focus, we are excited to rapidly execute our corporate strategy,” said Paul Bosse, President and Chief Executive Officer of Charleston Laboratories. The company will resubmit the CL-108 new drug application (NDA) in the coming weeks, and if approved, CL-108 can help the millions of acute pain patients who require an opioid analgesic while preventing or reducing opioid-induced nausea and vomiting (OINV).

“By addressing OINV, we believe that patients will achieve proper pain relief, shortened recovery time, and fewer days on opioid medication. Through decreasing a patient’s use of opioids, we aim to reduce the risk of misuse and abuse. Charleston Laboratories is dedicated to ensuring safe and responsible prescribing and use of our opioid analgesic portfolio,” said Bosse.

About Opioid-Induced Nausea & Vomiting (OINV)

Two of the most common side effects experienced by patients taking opioids for acute pain management are nausea^{1,2} and vomiting¹. In fact, approximately 40% of patients prescribed opioids for pain experience OINV.^{3,4} That translates to approximately 75 million instances of OINV in the US each year.³⁻⁷

OINV can be extremely burdensome for patients and presents barriers to achieving effective management of pain and recovery.³ Both healthcare professionals and patients have indicated that OINV was the primary reason for treatment discontinuation. Patients also stated a willingness to give up some degree of pain relief to mitigate the debilitating side effect that is OINV.³

The challenges of OINV are not limited to poor patient outcomes.³ The economic impacts of OINV include higher healthcare costs,³ longer recovery periods, and the need for additional patient care. Patients suffering from OINV showed increased utilization of inpatient and outpatient services, resulting in an increase of healthcare costs per patient, according to an analysis of claims data.³

About Charleston Laboratories, Inc.

Charleston Laboratories, Inc. is a privately held, specialty pharmaceutical company focused on the research, development and commercialization of novel pain products and technologies designed to prevent or reduce nausea and vomiting.

Charleston Laboratories' product pipeline seeks to address unmet needs in Opioid-Induced Nausea and Vomiting (OINV) and Migraine-Associated Nausea and Vomiting (MANV). Charleston Laboratories intends 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.

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