Charleston Laboratories, Inc. Resubmits NDA for CL-108

Jupiter, Florida – **October 17, 2017** – Charleston Laboratories, Inc. announced today that it resubmitted the new drug application (NDA) for its novel investigational treatment, CL-108, for the relief of moderate to severe acute pain while preventing and reducing opioid-induced nausea and vomiting (OINV) for patients with pain severe enough to require an opioid.

"I am pleased with all the hard work of our management team and the continued, unwavering support from our shareholders. Upon reacquiring the commercial rights to CL-108 our goal was to accelerate bringing this novel drug to market and resubmission marks the first critical step," said Paul Bosse, President and Chief Executive Officer of Charleston Laboratories. "The enthusiasm and understanding from potential commercial partners regarding the true unmet need in acute pain, reinforces our belief that CL-108 will redefine the treatment paradigm."

"Over the past year, we have intensified our engagement of key stakeholders in acute pain management within the areas of advocacy, education, access, and distribution to gain alignment regarding our commercialization strategy. Based on continual feedback and support, we are even more confident that our commercial plan represents a unique opportunity to create appropriate access for CL-108, a much needed and well-differentiated treatment. Our plan will emphasize responsible prescribing, distribution and safe use for the millions of acute pain sufferers," said Terrence Terifay, Chief Commercial Officer of Charleston Laboratories.

If approved, CL-108 may help acute pain patients who require an opioid analgesic while preventing and reducing OINV, thus providing patients a smoother recovery and reducing the need for continued use of opioid analgesics. Charleston Laboratories endeavors to create a new class of opioid analgesics supported by responsible labeling and dispensing strategies that will aid in efforts to minimize abuse and misuse.

About CL-108

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.

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 vomiting[1]. 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 acute 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 most bothersome 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 from 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 acute 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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