

## **Press Release**



### **Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. Receive Complete Response Letter from FDA for New Drug Application for CL-108 (hydrocodone, acetaminophen, promethazine) Tablets for Oral Use**

**Jupiter, FL, and Parsippany, NJ – February 3, 2017** – Charleston Laboratories, Inc., and Daiichi Sankyo, Inc., confirmed today that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for CL-108 (hydrocodone, acetaminophen, promethazine), an investigational treatment for the management of pain severe enough to require an opioid analgesic while preventing or reducing the associated opioid-induced nausea and vomiting when alternative treatments for pain are inadequate.

The CRL stated that the NDA in its present form was not approved and provided guidance on information needed to resolve matters identified. Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. intend to work closely with the FDA to address the points raised in this action.

#### **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. In August 2014, Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. entered into a strategic collaboration for the development and commercialization for the U.S. of hydrocodone combination products, including CL-108.

Charleston Laboratories' 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](http://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 a 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](http://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](http://www.dsi.com).

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