



## **Charleston Laboratories, Inc. and Daiichi Sankyo, Inc. Announce Completion of a Pharmacokinetics Study on CL-108**

**Jupiter, Florida, and Parsippany, NJ** –March 12, 2015 – Charleston Laboratories, Inc. and their co-development and co-commercialization partner, Daiichi Sankyo, Inc., announced the completion of a pharmacokinetics study on CL-108, Charleston Laboratories' lead product in development.

CL-108 is a tablet containing 7.5 mg of hydrocodone and 325 mg of acetaminophen with 12.5 mg of fast-absorbed promethazine. This novel therapy is being developed as a treatment for moderate to severe pain and the prevention of opioid-induced nausea and vomiting, or OINV.

"This study demonstrated that CL-108 provides comparable bioavailability of hydrocodone, acetaminophen and promethazine to commercial products," said Dr. Bernard Schachtel, Chief Scientific Officer at Charleston Laboratories.

"This is encouraging news," said Mr. Paul Bosse, President and Chief Executive Officer at Charleston Laboratories. "This study confirms the rationale for CL-108. With the clinical results from our first Phase 3 trial, these bioavailability results help explain why hydrocodone formulated with low-dose promethazine in CL-108 can help manage pain without the debilitating effects of nausea and vomiting that many patients experience from opioid treatment."

### **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 developed for the treatment of moderate to severe pain and the prevention of Opioid-Induced Nausea and Vomiting (OINV), the most common side effects of acute opioid therapy.

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](http://www.charlestonlabs.com).

### **About Daiichi Sankyo**

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, dyslipidemia and bacterial infections used by patients around the world, the Group has also launched treatments for thrombotic disorders and is building new product franchises. Furthermore, Daiichi Sankyo research and development is focused on bringing forth novel therapies in oncology and cardiovascular-metabolic diseases, including biologics. The Daiichi Sankyo Group has created a "Hybrid Business Model," to respond to market and customer diversity and optimize growth opportunities across the value chain. 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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