Charleston
LABORATORIES
Novel Innovation, Reducing Opioid Side Effects Patient by Patient

Charleston Laboratories, Inc. Announces Senior Global Regulatory Hire

Jupiter, Florida – February 14, 2017 – Charleston Laboratories, Inc. announced today that Mark A. Mannebach, Ph.D., R.Ph has joined its team as its Vice President of Global Regulatory Affairs & Quality Assurance. In his role, Mark will oversee and manage all regulatory submissions and renewals and will be responsible for developing the technical requirements of supply and quality agreements and other external contracts, specifically in relation to Charleston Laboratories' pipeline of products that address unmet needs such as Opioid-Induced Nausea and Vomiting (OINV) and Migraine-Induced Nausea and Vomiting (MINV), including co-promotion activities under its collaboration with Daiichi Sankyo.

"We're proud to add Mark to our already impressive senior leadership team," said Mr. Paul Bosse, President and Chief Executive Officer at Charleston Laboratories. "Mark's experience in regulatory and quality, coupled with his experience in the pain management industry, will make him a key member of the team."

Mark has more than 30 years of experience in the pharmaceutical industry in a variety of leadership roles at various major pharmaceutical companies including Parke-Davis/Warner-Lambert, Pharmacia, Baxter and Pfizer. For the past 8 years, Mark was the Vice President of Global Regulatory Affairs at Mallinckrodt where he spent a significant amount of his time overseeing the pain management portfolio. Mark has extensive experience working with the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) on a number of NDAs including 505(b)(2) applications. Mark had responsibility for the NDAs for the approved pain products Exalgo, Pennsaid (both 1.5% & 2% topical solutions), Xartemis XR, and Ofirmev.

"I was intrigued by the opportunity that Charleston Laboratories' pipeline and commercial strategy provides me professionally, to continue working in pain management," stated Dr. Mannebach. "I'm honored to join a team with such deep experience and a commitment to clinical and commercial excellence."

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 to prevent the burdensome side effects related to opioid analgesics and other analgesic products. In August 2014, the Company entered a strategic collaboration with Daiichi Sankyo for the development and U.S. commercialization of Charleston Laboratories' investigational hydrocodone-based products, including its lead candidate CL-108.

Charleston Laboratories' product pipeline 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 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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