BioDelivery Sciences Announces Clonidine Topical Gel for Painful Diabetic Neuropathy Phase 2b Trial Fails to Meet its Primary Efficacy Endpoint

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BDSI discontinues plan for further development resulting in an anticipated $16 million in operating plan savings in 2017 that extends cash runway

R&D efforts to focus on buprenorphine 30-day injection for opioid dependence and pain which complement BDSI's existing marketed products, BELBUCA® and BUNAVAIL®

RALEIGH, N.C., Dec. 13, 2016 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that its Phase 2b clinical study assessing the efficacy and safety of Clonidine Topical Gel for the management of painful diabetic neuropathy failed to show a statistically significant difference in pain relief between Clonidine Topical Gel and placebo. As a result, BDSI is discontinuing further development of the product at this time.

"We clearly indicated when we embarked on this study that following the changes we made to the protocol based on previous work, that the results would support a definitive decision," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "We can comfortably say that the changes made to the protocol design provided us with a reliable and unambiguous data set that demonstrated that Clonidine Topical Gel, at this strength and in this delivery form, is not effective for the treatment of painful diabetic neuropathy. As such, we have no further plans for development at this time, and the $16 million that was to be directed to this program for 2017 will now allow us to extend our cash runway into fourth quarter of next year."

Dr. Sirgo continued, "We will focus our R&D efforts on two important and exciting programs for our buprenorphine 30-day injection product in development - opioid dependence and chronic pain. Both are areas complimentary to BELBUCA and BUNAVAIL, where buprenorphine efficacy has previously been established with other products, and BDSI has considerable clinical expertise and regulatory experience with FDA."

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology and other drug delivery technologies to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs.

BDSI's development strategy focuses on the utilization of the FDA's 505(b)(2) approval process. This regulatory pathway creates the potential for more timely and efficient approval of new formulations of previously approved therapeutics.

BDSI's area of focus is the development and commercialization of products in the areas of pain management and addiction. These are areas where BDSI believes its drug delivery technologies and products can best be applied to address critical unmet medical needs. BDSI's marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain, painful diabetic neuropathy and opioid dependence. BDSI's headquarters is in Raleigh, North Carolina.

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