BioDelivery Sciences Provides Update on Ongoing Phase 3 Pivotal Trial for Clonidine Topical Gel for Painful Diabetic Neuropathy

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RALEIGH, N.C., Aug. 6, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced today that it has completed a pre-specified interim analysis of the ongoing initial pivotal Phase 3 trial for Clonidine Topical Gel for the treatment of painful diabetic neuropathy (PDN).

The interim analysis was performed on data from the first 50% of patients who completed the study. The purpose of the interim analysis was to allow for a sample size adjustment if necessary to maintain appropriate statistical power to detect a treatment effect between Clonidine Topical Gel and placebo.

BDSI views the outcome of the analysis as very encouraging. As a result of the interim analysis, a total of approximately 80 additional patients will be added to the ongoing trial in an effort to maintain 90% percent power to detect a statistically significant difference between Clonidine Topical Gel and placebo. The analysis was executed by an independent biostatistician.

"We are encouraged by the outcome of the interim analysis," stated Dr. Andrew Finn, Executive Vice President of Product Development at BDSI. "The additional patients not only allow us to maintain the probability of ultimately meeting the study's endpoints, but given that the initial study enrollment was about three months ahead of schedule, we still anticipate having top-line results by the end of the first quarter of 2015. In addition, the expanded sample size will provide an adequate number of subjects to complete the required long-term safety study that will be part of our NDA package. Also part of the NDA will be a second pivotal trial that we anticipate starting in early 2015."

"The outcome of the interim analysis is significant because it utilized actual study data to make a sample size adjustment to maintain the probability of a successful outcome," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "Based on this information we will continue to progress other aspects of the clinical development program necessary for the NDA."

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 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 particular 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 located in Raleigh, North Carolina.

For more information visit www.bdsi.com.

BDSI can now be followed on Facebook (Facebook.com/BioDeliverySI) and Twitter (Twitter.com/BioDeliverySI)

Cautionary Note on Forward-Looking Statements

This press release and any statements of representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the results of the Company's Phase 3 pivotal and safety studies of Clonidine Topical Gel) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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