BioDelivery Sciences Announces Completion of Randomization in Phase 3 Trial of Clonidine Topical Gel for the Treatment of Painful Diabetic Neuropathy

December 8, 2014

Top line data anticipated by end of first quarter 2015

RALEIGH, N.C., Dec. 8, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has completed the randomization of all patients in BDSI's ongoing initial pivotal Phase 3 clinical trial for Clonidine Topical Gel for the treatment of painful diabetic neuropathy (PDN). BDSI anticipates that topline results of the study will be available by the end of March 2015.

The Phase 3 trial is a multicenter, randomized, double-blind, placebo-controlled study to determine the efficacy and safety of Clonidine Topical Gel in the treatment of pain associated with PDN. In the trial, known as the RHAPSODY Study, subjects were randomized to receive either Clonidine Topical Gel or a placebo gel. Two hundred and sixty three adult subjects were randomized into the 12 week double-blind treatment phase of the study.

This is the first of two pivotal trials that would be required for submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA). FDA has granted Fast Track designation for the program, which recognizes the need of developing new therapies for this serious condition.

BDSI plans to begin the second Phase 3 study during the first quarter of 2015.

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 employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto (including, without limitation, at the presentations described herein) 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 clinical studies for, and FDA review 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 presentations or otherwise, except as required by applicable law.

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