BioDelivery Sciences Announces Primary Endpoint in Phase 3 Study of Clonidine Topical Gel for Painful Diabetic Neuropathy Not Met, Though Encouraging Results Support Continued Development

March 30, 2015

Previously announced interim data showed pain improvement compared to placebo; results not replicated in patients enrolled post interim analysis

Secondary efficacy endpoints statistically significant

Strong safety profile observed

BDSI to host 8:00am Eastern time conference call to discuss preliminary results

RALEIGH, N.C., March 30, 2015 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that the primary efficacy endpoint in the Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of painful diabetic neuropathy did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. In addition, a strong safety profile for the product was observed. The results of this trial provide data that will allow the company to better refine the protocol criteria to capture a more "enriched" patient population and target site selection.

"Based on the results of our previously announced positive interim analysis, this outcome was unexpected," said Dr. Andrew Finn, Executive Vice President of Product Development. "The interim analysis data showed a difference compared to placebo of -0.94 with a standard deviation of 2.2 which was close to our study assumption of -1.0 and 1.8, respectively, and very similar to the prior Phase 2 study conducted by our licensor Arcion."

Dr. Finn continued, "Based on the interim analysis, we added approximately 80 patients to the study. However, this added cohort of patients performed very differently than those assessed in the interim analysis, which lead to our outcome. Going forward, we are confident that the data from this study will provide us with the necessary information to enhance patient entry criteria, patient recruitment, and site selection."

"We believe the results of this trial continue to support that Clonidine Topical Gel is a potentially effective treatment for painful diabetic neuropathy and an important advance in treatment," stated Dr. Mark A. Sirgo, President and Chief Executive Officer. "We encountered similar challenges in our early clinical development work with BEMA Buprenorphine for chronic pain and were ultimately successful in conducting two pivotal studies that met their endpoints. Leveraging this experience and the aspects of this study that we believe are encouraging, we are optimistic that we can achieve a similar outcome with Clonidine Topical Gel."

Webcast Details

BDSI will host a webcast on Monday, March 30, at 8:00 a.m. Eastern time (5:00 a.m. Pacific time) to report results of the Phase 3 study of Clonidine Topical Gel for the treatment of painful diabetic neuropathy. The webcast can be accessed using the link included here or from the home page of the BDSI website (www.bdsi.com).

Domestic:	(855) 296-9625
International:	(920) 663-6273
Webcast:	http://edge.media-server.com/m/p/j77ikhvk

A replay of the webcast will be accessible on the BDSI website following conclusion of the call.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. 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, please visit or follow us:

Internet:	www.bdsi.com
Facebook:	Facebook.com/BioDeliverySI
Twitter:	@BioDeliverySI

Cautionary Note on Forward-Looking Statements

This press release, the presentation described herein, and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto (including, without limitation, at the webcast 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 any future clinical trials 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.

CONTACTS

Investors:
Matthew P. Duffy
Managing Director
LifeSci Advisors, LLC
212-915-0685
matthew@lifesciadvisors.com

Al Medwar
Vice President, Marketing and Corporate Development
BioDelivery Sciences International, Inc.
919-582-9050
amedwar@bdsi.com

Media:
Susan Forman/Laura Radocaj
Dian Griesel Int'l.
212-825-3210
sforman@dgicomm.com
lradocaj@dgicomm.com

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/biodelivery-sciences-announces-primary-endpoint-in-phase-3-study-of-clonidine-topical-gel-for-painful-diabetic-neuropathy-not-met-though-encouraging-results-support-continued-development-300057459.html

SOURCE BioDelivery Sciences International, Inc.