BioDelivery Sciences Provides Pipeline Update

December 18, 2015

Clonidine Topical Gel clinical trial for the treatment of painful diabetic neuropathy underway

R&D Day to take place in early 2016 providing updates on pipeline progress as well as on the launches of BUNAVAIL and BELBUCA

RALEIGH, N.C., Dec. 18, 2015 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) provided an update on its development pipeline and announced plans for an R&D day in early 2016.

BDSI has initiated its multi-center, randomized, double-blind, placebo controlled study to assess the efficacy and safety of Clonidine Topical Gel in the treatment of pain associated with painful diabetic neuropathy. The study design incorporates significant learnings from two previously conducted studies and involves tightened and additional inclusion criteria to improve assay sensitivity, reduce bias, and ensure compliance with enrollment criteria. BDSI expects the first patient to be enrolled shortly with study recruitment expected to be completed before the end of 2016.

"We believe that Clonidine Topical Gel is worthy of continued investigation based on our thorough analysis of all clinical trial data as well as the undeniable unmet need for new treatment options," said Dr. Andrew Finn, Executive Vice President of Product Development for BDSI. "We are employing innovative new tools to assist in limiting any potential investigator or patient bias, as is commonly seen in neuropathic pain trials. Using the data and resources we now possess, we believe the current study design and selection criteria will deliver results that will be definitive in determining the ability of clonidine to provide pain relief in this population. When the new refinements were applied to data from the prior trials, they had a net positive impact on the outcome. We look forward to discussing at our R&D day early next year these significant adjustments in the study inclusion criteria and impact on prior results as well as our confidence that these changes will lead us to a definitive outcome in the current study."

Additionally, BDSI continues to progress its 30 day buprenorphine injection. Following a recent pre-IND meeting with the U.S. Food and Drug Administration (FDA), BDSI will conduct one additional preclinical study to characterize the time for elimination of the formulation polymers at the injection site beyond the 30 day period of buprenorphine exposure. FDA requested this trial be part of the Investigational New Drug Application (IND) submission. Otherwise, FDA had minimal comments on the proposed first clinical study but provided added clarity on the pathway forward for development. The IND submission is now targeted for second quarter of next year.

Further details on the development programs for both Clonidine Topical Gel and Buprenorphine 30 Day Depot, as well as updates on the launch of BUNAVAIL (buprenorphine and naloxone) buccal film and BELBUCA (buprenorphine HCl) buccal film will be covered during an R&D day which BDSI is planning for early 2016. Further details on the event are forthcoming.

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, please visit or follow us:
Internet: www.bdsi.com
Facebook: Facebook.com/BioDeliverySI
Twitter: @BioDeliverySI

BDSI markets BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and *ONSOLIS*®(fentanyl buccal soluble film) (CII). BELBUCA™ (buprenorphine) buccal film (CIII) will be commercialized in the U.S. by Endo Pharmaceuticals pursuant to the worldwide licensing and development agreement between BDSI and Endo. For full prescribing information and important safety information on BDSI products, including BOXED WARNINGS for ONSOLIS and BELBUCA, please visit www.bdsi.com where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261.

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 presentation 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 clinical trials for the Company's products in development) 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.

Logo - http://photos.prnewswire.com/prnh/20110217/CL49801LOGO

SOURCE BioDelivery Sciences International, Inc.

For further information: 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