



## BioDelivery Sciences Announces Randomization Target Reached in Clinical Trial of Clonidine Topical Gel for the Treatment of Painful Diabetic Neuropathy

August 4, 2016

Top-line study results available by year-end

RALEIGH, N.C., Aug. 4, 2016 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has reached its target number of subjects to be randomized in its multi-center, double-blind, placebo-controlled Phase 2b study assessing the efficacy and safety of Clonidine Topical Gel in the treatment of pain associated with painful diabetic neuropathy. Based on the timing of randomization of the last patient, BDSI now expects topline results of the study will be available by the end of this year, which puts it six to eight weeks ahead of schedule.

BDSI initiated the Phase 2b study in late December 2015 to assess the efficacy and safety of Clonidine Topical Gel in the treatment of pain associated with painful diabetic neuropathy. Subjects in the study were randomized to receive either Clonidine Topical Gel or a placebo gel. A total of approximately 125 adult subjects will be randomized into the 12-week double-blind treatment phase of the study.

The U.S. Food and Drug Administration has granted Fast Track designation for the program, which recognizes the need for new therapies for this serious condition. If the present study objectives are met, BDSI expects to commence a confirmatory Phase 3 study in early 2017.

### **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<sup>®</sup>) 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 opioid dependence, chronic pain, breakthrough cancer pain and painful diabetic neuropathy. BDSI's headquarters is located in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet: [www.bdsi.com](http://www.bdsi.com)

Facebook: [Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI)

Twitter: @BioDeliverySI

**BDSI markets BUNAVAIL<sup>®</sup> (buprenorphine and naloxone) buccal film (CIII) and ONSOLIS<sup>®</sup>(fentanyl buccal soluble film) (CII). BELBUCA<sup>™</sup> (buprenorphine) buccal film (CIII) is 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, please visit [www.bdsi.com](http://www.bdsi.com) where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261. For full prescribing and safety information on BELBUCA, please visit [www.belbuca.com](http://www.belbuca.com).**

### **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 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 timing for announcement of the results of the clinical trial described herein, and the actual timing for any subsequent clinical trials) 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.

BDSI<sup>®</sup>, BEMA<sup>®</sup> and BUNAVAIL<sup>®</sup> are registered trademarks of BioDelivery Sciences International, Inc. The BioDelivery Sciences and BUNAVAIL logos are trademarks owned by BioDelivery Sciences International, Inc. All other trademarks and tradenames are owned by their respective owners.

© 2016 BioDelivery Sciences International, Inc. All rights reserved.

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](mailto:matthew@lifesciadvisors.com) or Al Medwar, Senior Vice President, Corporate and Business Development, BioDelivery Sciences International, Inc., 919-582-9050, [amedwar@bdsi.com](mailto:amedwar@bdsi.com); Media: Susan Forman/Laura Radocaj, Dian Griesel Int'l., 212-825-3210, [sforman@dgicomm.com](mailto:sforman@dgicomm.com) / [lradocaj@dgicomm.com](mailto:lradocaj@dgicomm.com)