BioDelivery Sciences Announces Completion of Patient Enrollment in its Initial Phase 3 Trial of Clonidine Topical Gel for Painful Diabetic Neuropathy

June 26, 2014

Top-line results anticipated by end-of-year

First potential topical product for painful diabetic neuropathy

RALEIGH, N.C., June 26, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has completed enrollment of all patients required for its initial Phase 3 study of Clonidine Topical Gel for the treatment of painful diabetic neuropathy (PDN).

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, referred to as the RHAPSODY Study, subjects are randomized to receive either Clonidine Topical Gel or a placebo gel. One hundred and forty adult subjects have been 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.

"We are very pleased with the rapid progression of this study, which we expect will allow for an independent interim analysis based on 50% of the patients completed during the third quarter of this year – one quarter ahead of schedule," said Dr. Andrew Finn, Executive Vice President of Product Development. "The expeditious enrollment of this study in part illustrates the significant unmet need that exists for new treatment options for patients suffering from painful diabetic neuropathy. Based on the enrollment of this trial, and assuming no additional patients will be required following the interim analysis, we should have top-line study results by the end of the year."

BDSI met with representatives of the FDA on November 21, 2013 to discuss the proposed clinical development program for Clonidine Topical Gel for the treatment of PDN. The FDA agreed with the overall clinical program proposed by BDSI, which includes two well controlled studies and one long-term safety study in patients suffering from PDN, the duration of treatment required for the safety assessment, the plan for data integration from prior and planned clinical studies and the interim analysis of the first pivotal trial. BDSI is now rolling over patients from the first Phase 3 trial into the 12-month long-term safety study and anticipates starting the second pivotal study in the first quarter of next year. The overall program is being conducted in subjects demonstrating functional skin nociceptors, which is the population of patients that demonstrated a statistically significant difference compared to placebo on the primary efficacy endpoint in a previously conducted Phase 2 study.

About Painful Diabetic Neuropathy and Topical Clonidine Gel

Nearly 26 million people in the U.S. have diabetes according to the American Diabetes Association. A substantial number of these people have peripheral neuropathy as manifest by impaired sensation and pain in the extremities, most often the feet. Patients with PDN often experience debilitating pain symptoms that affect day-to-day functioning and quality of life.

BDSI is currently studying whether Clonidine Topical Gel can relieve pain caused by PDN by decreasing the abnormal hyper-excitability of skin nociceptors. Currently available oral treatments are modestly effective in relieving symptoms and are limited by systemic side effects and drug interactions. There are no topical products approved for the treatment of PDN.

Oral medications that are approved for the treatment of PDN include anticonvulsants such as Lyrica (pregabalin), the antidepressant Cymbalta (duloxetine) and the opioid Nucynta (tapentadol), with sales for the treatment of neuropathic pain totaling over $3 billion in the U.S. according to Datamonitor. BDSI believes that Clonidine Topical Gel offers a novel mechanism of action to the available therapies with a potentially improved safety and tolerability profile. BDSI estimates annual peak sales potential for this product in excess of $300 million. BDSI is the worldwide licensee of development and commercialization rights to Clonidine Topical Gel for PDN under a license with Arcion Therapeutics.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. ("BDSI"®) (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.

The Company'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.

Cautionary Note on Forward-Looking Statements

This press release, the presentations referred to herein and any statements of 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 trials for, and FDA review of, Clonodine 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.

Readers are cautioned that peak sales and market size estimates have been determined on the basis of market research and comparable product analysis, but no assurances can be given that such estimates are accurate or that such sales levels will be achieved, if at all.

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

SOURCE BioDelivery Sciences International, Inc.

For further information: Investors: Brian Korb, Senior Vice President, The Trout Group LLC, (646) 378-2923, bkorb@troutgroup.com, or Al Medwar, Vice President, Marketing and Corporate Development, BioDelivery Sciences International, Inc., 919-582-9050, amedwar@bdsi.com