BioDelivery Sciences Announces Randomization of Over 50% of Subjects in its Initial Phase 3 Study of Clonidine Topical Gel for Painful Diabetic Neuropathy

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Faster than projected enrollment moves anticipated interim analysis up to third quarter 2014

RALEIGH, N.C., May 6, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has randomized more than half of the planned number of patients required for its ongoing initial Phase 3 study of Clonidine Topical Gel, BDSI's proposed treatment for painful diabetic neuropathy (PDN).

The intent of the study will be to demonstrate the efficacy and safety of Clonidine Topical Gel for the treatment of PDN. An interim analysis of the study, which will be based on the first 50% of patients entering the study, is now anticipated to occur in the third quarter of 2014. It was earlier projected based on estimated patient enrollment the interim analysis would occur in fourth quarter of this year. The purpose of the interim analysis is to confirm the assumptions regarding the study sample size and allow for an increase if needed.

"Early enrollment in our RHAPSODY study is ahead of schedule as we are using very experienced investigative sites with substantial patient populations with painful diabetic neuropathy, allowing us to get to our interim results earlier," said Dr. Andrew Finn, Executive Vice President of Product Development. "We anticipate this rate of enrollment may not be sustained as the initial backlog of patients subsides; however, if no additional patients are needed following the interim analysis, it is possible that we may have final results prior to first quarter of 2015. We will provide future updates on the timing of study completion."

The Phase 3 trial, known as the RHAPSODY Study, is a multicenter, randomized, double blind, placebo controlled study to determine the efficacy and safety of Clonidine Topical Gel in the treatment of PDN. The study is being conducted in subjects with 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 performed Phase 2 study. Approximately 140 adult subjects will be randomized to receive either Clonidine Topical Gel or a placebo gel for a period of 12 weeks.

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.

Clonidine Topical Gel is thought to relieve pain 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 this painful condition.

Oral medications that are approved for the treatment of painful diabetic neuropathy 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 painful diabetic neuropathy under a license with Arcion Therapeutics.

About BioDelivery Sciences International

BioDelivery Sciences International (NASDAQ: BDSI) is a specialty pharmaceutical company that is leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. BDSI is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

BDSI's pain franchise consists of three products, two of which utilize the patented BioErodible MucoAdhesive (BEMA) drug delivery technology. ONSOLIS (fentanyl buccal soluble film) is approved in the U.S., Canada, E.U. (where it is marketed as BREAKYL) and Taiwan (where it will be marketed as PAINKYL), for the management of breakthrough pain in opioid tolerant, adult patients with cancer. The commercial rights are licensed to Meda for all territories worldwide except for Taiwan (licensed to TTY Biopharm) and South Korea(licensed to Kunwha Pharmaceutical Co.).

BEMA Buprenorphine is in Phase 3 clinical trials for the treatment of moderate to severe chronic pain and is licensed on a worldwide basis to Endo Pharmaceuticals. Clonidine Topical Gel for the treatment of painful diabetic neuropathy is currently in Phase 3 development.

An NDA for BUNAVAIL, a BEMA formulation of buprenorphine in combination with naloxone, is currently under review for the maintenance treatment of opioid dependence and has a PDUFA date of June 7, 2014.

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 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 FDA's review of BUNAVAIL, the results of the Company's commercial efforts for BUNAVAIL, and the results of the Company's clinical trials for BEMA Buprenorphine and 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 events or otherwise, except as required by applicable law.

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