BioDelivery Sciences Announces Enrollment of the First Patient in a Phase 3 Clinical Study of Clonidine Topical Gel for Painful Diabetic Neuropathy

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Product has fast track designation by FDA

Potential to be the first topical treatment approved for painful diabetic neuropathy

RALEIGH, N.C., April 3, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (Nasdaq: BDSI) announced today the enrollment of the first patient in the RHAPSODY Study, a Phase 3 clinical trial of Clonidine Topical Gel for the treatment of painful diabetic neuropathy.

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 painful diabetic neuropathy. The study will be 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. In the RHAPSODY Study subjects will be randomized to receive either Clonidine Topical Gel or a placebo gel. Approximately 140 adult subjects will be randomized into the study, which includes a double blind treatment phase of 12 weeks.

"We are very pleased to be moving another important clinical program into Phase 3 development," said Dr. Andrew Finn, Executive Vice President of Product Development. "There is a significant unmet need for new treatment options for patients suffering from painful diabetic neuropathy, and we look forward to progressing enrollment forward and toward anticipated interim results during the fourth quarter of this year followed by final study results in the first quarter of 2015."

"BDSI plans to conduct an independent interim analysis based on 50% of the patients completed," said Adrian Hepner, MD, Vice President of Clinical Research. "We anticipate that results of the interim analysis will be available in the fourth quarter of this year, and if the results confirm current study assumptions, the second Phase 3 trial of similar size and scope will be initiated at that time. This timeline could allow for a 2016 NDA submission."

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 painful diabetic neuropathy (also known as 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 painful diabetic neuropathy, 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. FDA also confirmed Fast Track designation for the program which recognizes the need of developing new therapies for this serious condition.

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 currently consists of three products. ONSOLIS® (fentanyl buccal soluble film) is approved in the U.S., Canada, and the E.U. (where it is marketed as BREAKYL™), 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, which is licensed on a worldwide basis to Endo Pharmaceuticals, is currently in Phase III development for the treatment of moderate to severe chronic pain. Clonidine Topical Gel is expected to enter Phase III trials in the first quarter of 2014 for the treatment of painful diabetic neuropathy. BUNAVAIL™, a BEMA formulation of buprenorphine and naloxone, is currently under review by FDA for the maintenance treatment of opioid dependence and has a PDUFA date of June 7, 2104.

BDSI's headquarters is located in Raleigh, North Carolina. For more information, visit www.bdsi.com.

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This press release and any statements of representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto 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 and regulatory activities for Clonidine Topical Gel described herein) 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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For further information: Brian Korb, Senior Vice President, The Trout Group LLC, (646) 378-2923, bkorb@troutgroup.com; Al Medwar, Vice President, Marketing and Corporate Development, BioDelivery Sciences International, Inc., 919-582-9050, amedwar@bdsi.com