BioDelivery Sciences Announces Four BUNAVAIL Abstracts to be Presented at the 2014 American Society of Addiction Medicine Annual Conference

January 30, 2014

First presentation of detailed BUNAVAIL clinical data scheduled for April 11 and 13, 2014

BUNAVAIL NDA has a PDUFA action date of June 7, 2014

RALEIGH, N.C., Jan. 30, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) today announced that data from clinical studies of BUNAVAIL have been accepted for presentation at the American Society of Addiction Medicine (ASAM) 45th Annual Medical-Scientific Conference, April 10-13, 2014 in Orlando, Florida.

(Logo: http://photos.prnewswire.com/prnh/20110217/CL49801LOGO)

Four abstracts will be presented highlighting data from the clinical development program, which incudes the pivotal bioequivalence study of BUNAVAIL compared to Suboxone tablets and a safety study conducted in 249 subjects undergoing maintenance treatment for opioid dependence with Suboxone film or tablets who were converted to BUNAVAIL for 12 weeks.

"We are honored to have multiple abstracts accepted to such a prestigious addiction medicine forum and to publicly present this data for the first time," said Andrew L Finn, Pharm D, Executive Vice President of Product Development at BDSI. "The data will highlight the unique pharmacokinetic characteristics and the clinical profile of BUNAVAIL as well as the high acceptance of BUNAVAIL by patients who converted from Suboxone therapy."

The New Drug Application for BUNAVAIL is currently under review by the U.S. Food and Drug Administration with a PDUFA date of June 7, 2014.

BUNAVAIL utilizes BDSI's proprietary BioErodible MucoAdhesive (BEMA) technology to deliver buprenorphine for the maintenance treatment of opioid dependence, along with the opioid antagonist naloxone, which is intended to serve as an abuse deterrent. BUNAVAIL was designed to efficiently and conveniently deliver buprenorphine while potentially overcoming some of the challenges with other dosage forms.

Presentation Titles and Session Details

Oral presentation by Kent Hoffman, DO
Buprenorphine/Naloxone Buccal Film is Well Tolerated in Opioid - Dependent Patients Converted from Suboxone
Sunday, April 13, 2014, 8:00 am – 10:00 am

Poster presentation by Gregory B. Sullivan, MD
Buprenorphine/Naloxone Buccal Film: A Novel Approach in the Treatment of Opioid Dependence
Friday, April 11, 2014, 12:30 pm – 2:30 pm

Poster presentation by Niraj Vasisht, PhD, Senior Vice President, Product Development and Chief Technical Officer of BDSI
Buprenorphine/Naloxone Buccal Film: Relative Buprenorphine Bioavailability Approximately Twice that of Suboxone
Friday, April 11, 2014, 12:30 pm – 2:30 pm

Poster presentation by Lynn Webster, MD
Low-Dose Naloxone Provides an Abuse Deterrent Effect to Buprenorphine Doses
Friday, April 11, 2014, 12:30 pm – 2:30 pm

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 3 development for the treatment of moderate to severe chronic pain. Clonidine Topical Gel is expected to enter Phase 3 trials in 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.

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

owned by their respective owners.

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) 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.

SOURCE BioDelivery Sciences International, Inc.

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