BioDelivery Sciences Announces BEMA Buprenorphine NDA Submission on Track following Pre-NDA Meeting with FDA

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BEMA Buprenorphine on track for late 2014 or early 2015 NDA filing by partner Endo Pharmaceuticals

RALEIGH, N.C., Aug. 12, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that along with its commercial partner, Endo Pharmaceuticals, engaged in a positive pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding BEMA Buprenorphine for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate. The meeting was held on July 15 and meeting minutes have been received.

The positive outcome of the pre-NDA meeting allows BDSI and Endo to maintain expectations of an NDA filing with FDA for BEMA Buprenorphine in late 2014 or early 2015 as planned.

The scheduled meeting with FDA regarding the NDA submission for BEMA Buprenorphine was undertaken to review the key data elements for the NDA and follows the successful completion of two Phase 3 clinical studies of BEMA Buprenorphine. Both studies yielded positive top-line results and demonstrated that BEMA Buprenorphine significantly improved chronic pain relief compared to placebo in a study of opioid naive patients ($p<0.005$) and in a study of opioid experienced patients ($p<0.0001$). Secondary endpoints were also supportive of the efficacy.

"We are pleased to be progressing another product toward an NDA submission," said Dr. Andrew Finn, Executive Vice President of Product Development. "We will continue to work closely with our partner Endo Pharmaceuticals as they prepare the NDA submission for late this year or early next year."

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®) 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 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.

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Cautionary Note on Forward-Looking Statements

This press release, the interview described and presented 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 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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