Endo Pharmaceuticals and BioDelivery Sciences Announce NDA Submission for Buprenorphine HCl Buccal Film for the Management of Moderate to Severe Chronic Pain

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DUBLIN and RALEIGH, N.C., Dec. 23, 2014 /PRNewswire/ -- Endo Pharmaceuticals Inc., a subsidiary of Endo International plc (NASDAQ: ENDP) (TSX: ENL), and BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced today that they have submitted a New Drug Application (NDA) for Buprenorphine HCl Buccal Film to the U.S. Food and Drug Administration (FDA). Buprenorphine HCl Buccal Film is under development for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

The drug uses BDSI's patented BioErodible MucoAdhesive (BEMA®) drug delivery technology to efficiently and conveniently deliver buprenorphine across the buccal mucosa (inside lining of the cheek). Buprenorphine, a Schedule III controlled substance, is a partial opioid agonist and a potent analgesic with a relatively long duration of action. Buprenorphine HCl Buccal Film is being developed and will be commercialized through a worldwide license and development agreement between Endo Pharmaceuticals and BDSI.

"Buprenorphine HCl Buccal Film is Endo's lead development program for our branded pharmaceuticals business representing a potentially important addition to our portfolio of pain medicines," said Rajiv De Silva, President and CEO of Endo. "Today's NDA filing is a significant step forward in our effort to address a need among patients suffering chronic pain. As a leader in the treatment of chronic pain, Endo has extensive experience supporting patients and their physicians, and look forward to continuing that commitment with Buprenorphine HCl Buccal Film."

The two pivotal phase 3 studies for demonstration of safety and efficacy were double-blind randomized, placebo-controlled, enriched-enrollment studies in patients with chronic lower back pain. One study (BUP-307) was conducted in opioid experienced subjects, and the second study (BUP-308) was conducted in subjects naïve to opioid therapy. Both studies met the primary efficacy endpoint of change from baseline to week 12 of mean daily pain intensity score from placebo (BUP- 307; p <.00001 ; BUP – 308; p= .001). Buprenorphine HCl Buccal Film was generally well tolerated demonstrating a low incidence of typical opioid like side effects.

"The submission of the NDA for Buprenorphine HCl Buccal Film is a major milestone in BDSI's partnership with Endo Pharmaceuticals," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "Buprenorphine's role in pain management in the United States has always been hampered by the lack of a convenient and flexible dosage form. We believe our patented BEMA technology will overcome this obstacle and provide physicians with a meaningful product to treat chronic pain. We look forward to continuing our work with Endo, and making this therapy available to patients who need it."

About Endo International plc

Endo International plc is a global specialty healthcare company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets, and distributes quality branded pharmaceutical, generic pharmaceutical, over the counter medications and medical device products through its operating companies. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

About Endo Pharmaceuticals Inc.

Endo Pharmaceuticals Inc. is focused on developing and delivering high-value branded pharmaceutical products that meet the unmet needs of patients. Endo Pharmaceuticals is an operating company of Endo International plc (NASDAQ: ENDP) (TSX: ENL), a global specialty healthcare company focused on improving patients' lives while creating shareholder value. Learn more at www.endo.com.

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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect Endo's and BDSI's

current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Although Endo and BDSI believe that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo with the Securities and Exchange Commission ("SEC") and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR"), and by BDSI with the SEC, including under the caption "Risk Factors" in Endo Health Solutions Inc.'s Form 10-K and Endo's Form 10-Q and Form 8-K filings, and in BDSI's Form 10-K, Form 10-Q and Form 8-K filings, as applicable, and as otherwise enumerated herein or therein, could affect Endo's and/or BDSI's future financial results and could cause Endo's and/or BDSI's actual results to differ materially from those expressed in forward-looking statements contained in this communication. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause Endo's and/or BDSI's actual results to differ materially from expected and historical results. Neither Endo nor BDSI assume any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities law.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/endo-pharmaceuticals-and-biodelivery-sciences-announce-nda-submission-for-buprenorphine-hcl-buccal-film-for-the-management-of-moderate-to-severe-chronic-pain-300013786.html

SOURCE Endo Pharmaceuticals Inc.; BioDelivery Sciences International, Inc.

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