Endo Pharmaceuticals and BioDelivery Sciences Announce Acceptance of NDA for BELBUCA™ (buprenorphine HCl) Buccal Film for the Management of Chronic Pain

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DUBLIN and RALEIGH, N.C., Feb. 23, 2015 /PRNewswire/ -- Endo Pharmaceuticals Inc., a subsidiary of Endo International plc (NASDAQ: ENDP) (TSX: ENL), and BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced today that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for the companies' BELBUCA™ (buprenorphine HCl) buccal film 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. FDA has indicated a standard review designation for the NDA and therefore the action date is expected 10 months from the NDA submission (October 2015).

Additionally, the FDA recently accepted BELBUCA as the proprietary name for (buprenorphine HCl) buccal film.

"Today's NDA acceptance represents an important step forward in our commitment to bringing to patients new therapeutic options for the treatment of chronic pain. We believe that BELBUCA is a significant advancement in pain care, and an important extension to Endo's portfolio of products," said Rajiv De Silva, President and CEO of Endo. "We look forward to working closely with the FDA and with our partner, BDSI, during this review period."

Buprenorphine is a Schedule III controlled substance, meaning that it has been designated as having lower abuse potential than Schedule II drugs, a category which includes most opioid analgesics. Buprenorphine is a mu-opioid receptor partial agonist and a potent analgesic with a relatively long duration of action. BELBUCA is being developed and will be commercialized through a worldwide license and development agreement between Endo Pharmaceuticals and BDSI.

"The FDA's acceptance of our BELBUCA NDA is a significant milestone for BDSI and in our partnership with Endo," said Dr. Mark A. Sirgo, President and CEO of BDSI. "We believe that BELBUCA can offer those suffering with chronic pain with a novel treatment approach. We look forward to continuing our work with Endo, and making this therapy available to patients who need it."

About BELBUCA Phase 3 Development
Two pivotal Phase 3 studies were conducted to demonstrate the safety and efficacy of BELBUCA. The studies 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). BELBUCA was generally well-tolerated, demonstrating a low incidence of typical opioid like side effects.

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 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.

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