Endo and BioDelivery Sciences announce positive top-line results from the Phase III clinical trial of BEMA® buprenorphine in opioid-experienced patients with chronic pain

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- Pre-NDA meeting scheduled with FDA in July

DUBLIN and RALEIGH, N.C., July 7, 2014 /PRNewswire/ -- Endo Pharmaceuticals Inc., a subsidiary of Endo International plc (NASDAQ: ENDP) (TSX: ENL), and BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced today positive top-line results from its pivotal Phase III efficacy study of BEMA buprenorphine in opioid-experienced patients. BEMA buprenorphine is being developed 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 in both patients who are opioid naive and opioid experienced.

The trial successfully met its primary efficacy endpoint in demonstrating that BEMA buprenorphine resulted in significantly ($p<0.0001$) improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BEMA buprenorphine compared to placebo. The most commonly reported adverse events in patients treated with buprenorphine compared to placebo were nausea (7.5% vs. 7.4%) and vomiting (5.5% vs. 2.3%).

"We are highly encouraged by today's announced study results, which we believe are meaningful for appropriate patients requiring an opioid," said Dr. Susan Hall, executive vice president, chief scientific officer and global head of research and development and quality. "And we look forward to now focusing on our upcoming pre-NDA meeting this month with FDA followed by the preparation and submission of our NDA for BEMA buprenorphine as soon as possible."

"We are extremely pleased with this robust and significant outcome from this trial in opioid-experienced patients and look forward to sharing more of the results from this study and the positive results from the earlier opioid-naive study at upcoming medical conferences," said Dr. Mark A. Sirgo, President and CEO of BDSI. "In addition, the locking of the database for the opioid-experienced study has triggered a $10 million milestone payment from Endo per our licensing agreement. We look forward to working with Endo toward the completion of the NDA."

"BEMA buprenorphine is an important development program for Endo," said Rajiv De Silva, President and CEO of Endo. "Our U.S. Branded Pharmaceuticals team has extensive experience supporting pain therapeutics and this program represents a significant opportunity to continue to leverage our commercial capabilities, if we are successful with our application for approval."

About the Phase III BEMA buprenorphine trial in opioid-experienced patients

The Phase III clinical trial was an enriched-enrollment, double-blind, randomized withdrawal study to evaluate the efficacy and safety of BEMA buprenorphine in the treatment of chronic lower back pain in opioid-experienced patients. A total of 511 patients who titrated to a well-tolerated, effective dose were randomized to either continue on that dose of BEMA buprenorphine, or receive placebo (BEMA film with no active drug), with treatment continuing for 12 weeks. The primary efficacy endpoint was the mean change in the daily average pain numerical rating scale (NRS-Pain) scores from baseline (just prior to randomization) to week twelve of the double-blind treatment period. Pain was self-reported daily on an 11-point numeric rating scale (daily NRS; 0=no pain, 10=worst possible pain).

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 and device products through its operating companies. Endo has global headquarters in Dublin, Ireland, and US headquarters in Malvern, PA. Learn more at www.endo.com.

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. 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, Endo Health Solutions Inc. ("EHSI") and BDSI with securities regulators in the United States and Canada including under the caption "Risk Factors" in EHSI's and BDSI's Form 10-K, and Endo's and BDSI's Form 10-Q and Form 8-K filings, as applicable, with the Securities and Exchange Commission and by Endo with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR") 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 EHSI's and BDSI's Annual Report on Form 10-K. 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.

SOURCE Endo Pharmaceuticals Inc.

Endo International plc, Investors/Media: Blaine Davis, +353-1-669-6635, (484) 216-7158, Investors: Jonathan Neely, (484) 216-6645, Media: Brian O'Donnell, (484) 216-6726; BioDelivery Sciences International, Investors: Al Medwar, VP, Marketing and Corporate Development, (919) 582-9050, Investors: Brian Korb, Senior Vice President, The Trout Group, (646) 378-2923, Media, Susan Forman or Laura Radocaj, Dian Griesel International, 212-825-3210