Endo and BioDelivery Sciences Announce Positive Top-Line Results from the Phase III Clinical Trial of BEMA Buprenorphine in Opioid Naïve Patients with Chronic Pain

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MALVERN, Pa and RALEIGH, N.C., – Jan. 23, 2014 – Endo Pharmaceuticals Inc., a subsidiary of Endo Health Solutions Inc. (Nasdaq: ENDP), and BioDelivery Sciences International, Inc. (Nasdaq: BDSI) announced today positive top-line results from its pivotal Phase 3 efficacy study of BEMA buprenorphine in opioid- "naïve" subjects. BEMA buprenorphine is being developed for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy for an extended period of time in both patients who are opioid naïve and opioid experienced.

The trial successfully met its primary efficacy endpoint in demonstrating that BEMA buprenorphine resulted in significantly ($p<0.005$) 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 (10% vs. 8%), vomiting (4% vs. 2%) and constipation (4% vs. 2%).

"We are encouraged by today's announced study results, which we believe are meaningful for patients suffering from moderate to severe chronic pain," said Dr. Ivan Gergel, executive vice president of research and development Endo. "And we look forward to providing additional updates in mid-2014 regarding the BEMA buprenorphine chronic pain program."

"We are obviously pleased with the outcome from this trial in opioid naïve patients and look forward to the upcoming results of the Phase 3 study for BEMA Buprenorphine for the treatment of chronic pain in opioid experienced patients," said Dr. Mark A. Sirgo, President and CEO of BDSI. "In addition to these positive and encouraging results, the locking of the database for the opioid naïve study has triggered a $10 million milestone payment from Endo per our licensing agreement. We will receive a similar milestone payment related to the completion of the opioid experienced study and if successful, the potential for an NDA submission by late this year."

The second Phase 3 clinical study of BEMA Buprenorphine in an opioid "experienced" patient group is ongoing. Based on recruitment rates in this study, the database for this trial is anticipated to be locked by mid-2014, with results to follow shortly thereafter.

About the Phase 3 BEMA Buprenorphine Trial in Opioid Naïve Patients

The Phase 3 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 naive patients. A total of 462 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

Endo Health Solutions Inc. is a U.S.-based specialty healthcare company with four distinct business segments that are focused on branded and generic pharmaceuticals, devices and services and provide quality products to its customers while improving the lives of patients. Through its operating companies - AMS, Endo Pharmaceuticals, HealthTronics and Qualitest - Endo is dedicated to finding solutions for the unmet needs of patients.

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. 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. Investors should note that many factors, as more fully described under the caption "Risk Factors" in Endo's and BDSI's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and as otherwise enumerated herein or therein, could affect Endo's and BDSI's future financial or other results and could cause Endo's and BDSI's actual results (including, without limitation, the results of the opioid "experienced" trial described herein and the results of regulatory review of BEMA Buprenorphine) to differ materially from those expressed in forward-looking statements contained herein. 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 our 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.

CONTACT

Endo Health Solutions, Inc.

Investors/Media: Blaine Davis (484) 216-7158: Investors: Jonathan Neely (484) 216-6645: Media: Brian O'Donnell (484) 216-6726

BioDelivery Sciences International

Al Medwar, VP, Marketing and Corporate Development (919) 582-9050

Brian Korb, Senior Vice President, The Trout Group (646) 378-2923