Endo Will Showcase Late-Breaking Phase 3 CCH Data at the 2019 American Academy of Dermatology Annual Meeting

March 1, 2019

Endo To Present Data From Two Abstracts on Collagenase Clostridium Histolyticum

DUBLIN, March 1, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that it will present new data showing collagenase clostridium histolyticum (CCH) significantly met the clinical endpoint of improved cellulite severity and appearance and was well tolerated in recent Phase 3 clinical trials. The Phase 3 data will be presented on March 2, 2019 during the 'Late-breaking Research: Procedural Dermatology' session at the 2019 Annual Meeting of the American Academy of Dermatology (AAD) taking place in Washington, DC.

The RELEASE-1 and RELEASE-2 Phase 3 studies, which were identically designed, randomized, double blinded and placebo-controlled, assessed the efficacy, safety and tolerability of CCH for the treatment of cellulite in women. A greater percentage of the 843 women treated during the studies (CCH vs. placebo: RELEASE 1, n=210 vs n=213; RELEASE-2, n=214 vs n=206) met the primary endpoint of response with CCH versus placebo in both the RELEASE-1 (P=0.006) and RELEASE-2 (P=0.002) studies.

"Our Phase 3 clinical trial program exhibited promising results and we are pleased to present the late-breaking data at the AAD Annual Meeting, a trusted, dependable source of dermatologic education," said Matthew Davis, M.D., R.Ph., Endo's Senior Vice President and Chief Medical Officer. "We greatly appreciate the patients and investigators who participated in these studies, which helped further our understanding of the potential for CCH, if approved, as an important new treatment for cellulite."

In addition, statistically significant improvements with CCH versus placebo were observed for 8 of 8 (RELEASE-1) and 7 of 8 (RELEASE-2) secondary endpoints. Other patient-centric endpoints were also evaluated, including improvement in the Subject Global Aesthetic Improvement Scale (S-GAIS), a 5-point scale rating global aesthetic improvement in appearance, compared to pretreatment, as judged by the subject. Most adverse events observed in CCH-treated patients were mild/moderate and injection-site related (e.g., bruising, pain, nodule, pruritus, erythema, and discoloration).

"I see patients on a regular basis who are embarrassed and uncomfortable about their cellulite, yet there are currently limited effective treatment options available," said Joely Kaufman-Janette, M.D., a board-certified dermatologist at Skin Associates of South Florida, and the presenter of the CCH clinical trial abstract. "These Phase 3 results reinforce the promise of CCH as a potential new injectable option to treat cellulite, which would be very meaningful to patients and could significantly impact the aesthetics landscape."

Additionally, an encore e-poster presentation of the Human Pharmacokinetics of Subcutaneous CCH and Preclinical Safety of Inadvertent Intravenous Administration will be available for viewing at the AAD Annual Meeting.

About RELEASE-1 and RELEASE-2
RELEASE-1 and RELEASE-2 are two identical, multicenter, randomized, double-blind, placebo-controlled studies that enrolled 845 women aged 18 years or older in the United States with moderate to severe cellulite. Each subject received up to three treatments of CCH (0.84 mg / treatment area) or placebo with each treatment session occurring approximately 21 days apart. Up to twelve injections were administered during each session across each treatment area – the left and right buttock. At both the outset and conclusion of each treatment, cellulite severity was assessed by each patient and clinician using two validated photonumeric cellulite severity scales developed by Endo and third-party psychometric experts.

ABOUT CELLULITE
Cellulite is a localized alteration in the contour of the skin that has been reported in 85 to 98 percent of post-pubertal females and affects women of all races and ethnicities.[1,2] The primary cause of the condition is a thickening of the collagen septae that attach the skin to the underlying fascia layers with additional contributing protrusions of subcutaneous fat. The septae tether the skin, which causes the surface dimpling characteristic of cellulite.[2,3] . Cellulite clinically presents on the buttocks, thighs, lower abdomen and arms.

It is known that cellulite is different from generalized obesity. In generalized obesity, adipocytes undergo hypertrophy and hyperplasia that are not limited to the pelvis, thighs, and abdomen.[4] In areas of cellulite, characteristic large, metabolically stable adipocytes have physiologic and biochemical properties that differ from adipose tissue located elsewhere. Weight gain may make cellulite more noticeable, but it may be present even in thin subjects.

Despite multiple therapeutic approaches for the attempted treatment of patients with cellulite, there are currently no FDA-approved injectable treatment on the market.[5]

About Endo International plc
Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation, including, but not limited to, the statement by Drs. Davis and Kaufman-Janette, and other statements regarding research and development outcomes, efficacy, adverse reactions, market and product potential and product availability. 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 current views, expectations and beliefs concerning future events, they involve risks and uncertainties. Although Endo believes 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 and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval, including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings, and as otherwise enumerated herein or therein, could affect Endo's future results and could cause Endo'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. Endo assumes no 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 laws.

References

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