Collagenase Clostridium Histolyticum For The Investigational Treatment Of Cellulite To Be Featured During The Hot Topics Symposium At The Aesthetic Meeting 2018

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DUBLIN, April 27, 2018 /CNW/ -- Endo International plc (NASDAQ: ENDP) today announced the presentation of clinical data from a Phase 2b investigational study of collagenase clostridium histolyticum (CCH) for the treatment of cellulite. Dr. Lawrence Bass, a New York City-based, board-certified plastic surgeon, will present the data this afternoon during the Premier Global Hot Topics session, a highlight of The Aesthetics Meeting 2018, the annual meeting of the American Society for Aesthetic Plastic Surgery (ASAPS), held at the Marriott Marquis in New York City.

"Hot Topics, one of the most popular sessions at the annual meeting, is about new and emerging technologies in aesthetic plastic surgery," said ASAPS-member Dr. Bass. "Despite the number of options currently marketed as cellulite remedies, there still are no U.S. Food and Drug Administration (FDA)-approved injectable treatments, so there is great interest from my peers regarding this investigational study."

The Phase 2b trial enrolled 375 women with moderate or severe cellulite aged 18 years or older in the United States. Each subject received up to three treatment sessions of CCH (0.84 mg / session) or placebo with each treatment session occurring approximately 21 days apart. Twelve injections were administered into cellulite dimples during each session across an entire treatment quadrant – left or right buttock or left or right posteriolateral thigh. A statistically significant proportion of CCH subjects reported being "Satisfied" or "Very Satisfied" with their cellulite treatment, compared to placebo subjects. CCH was well-tolerated by all dose groups. Most adverse events (AEs) reported as being mild to moderate and primarily limited to the local injection area; 92 percent of all related AEs were mild to moderate in the CCH group compared to 96 percent in the placebo group; the most common AEs were expected and included injection site bruising (approximately 75 percent) and injection site pain (approximately 59 percent).

"We are pleased that the data from this study will be presented at the premier aesthetic plastic surgery meeting," said Matthew Davis, M.D., R.Ph., Senior Vice President, Research and Development Branded Pharmaceuticals of Endo Pharmaceuticals. "Aesthetic physicians look to this session for scientifically driven and data-based solutions; being highlighted at Hot Topics is an important milestone in Endo's development program of CCH for Cellulite as we pursue entry into the Medical Aesthetics community."

Earlier this year Endo announced the initiation of two identical Phase 3 RELEASE* clinical trials. The multicenter, randomized, double-blind, placebo-controlled trials are expected to enroll 840 women (420 in each trial) aged 18 years or older with moderate to severe cellulite in the United States.

About the American Society for Aesthetic Plastic Surgery
The American Society for Aesthetic Plastic Surgery is recognized as the world's leading organization devoted entirely to aesthetic plastic surgery and cosmetic medicine of the face and body. ASAPS is comprised of over 2,600 Plastic Surgeons; Active Members are certified by the American Board of Plastic Surgery (USA) or by the Royal College of Physicians and Surgeons of Canada and have extensive training in the complete spectrum of surgical and non-surgical aesthetic procedures. International Active Members are certified by equivalent boards of their respective countries.

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.[i],[ii] 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.[ii],[iii] CCH is intended to target and lyse, or break, those collagen tethers with the goal of releasing the skin dimpling and potentially resulting in smoothing of the skin. Despite multiple therapeutic approaches for the attempted treatment of cellulite, there are no FDA-approved pharmacological treatments.[iv]

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.

About Endo Pharmaceuticals Inc.
Endo Pharmaceuticals Inc., headquartered in Malvern, PA, develops and markets high-value, quality branded pharmaceutical products for patients in need. Endo Pharmaceuticals' specialty portfolio includes products for urology, men's health, orthopedics and endocrinology, with product development underway in medical aesthetics. Endo Pharmaceuticals is an operating company of Endo International plc. Learn more at www.endo.com or www.endopharma.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 statements by Drs. Bass and Davis, 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.

* **R**andomized **E**va**L**uation of C**E**llulite Reduction by Coll**A**gena**SE** Clostridium Histolyticum (RELEASE)

[i] Avram M. Cellulite: a review of its physiology and treatment, *Journal of Cosmetic Laser Therapy* 2004; 6: 181–185.
[ii] Khan MH et al. Treatment of cellulite: Part I. Pathophysiology. *J Am Acad Dermatol*. 2010 Mar;62(3):361-70.
[iii] Querleux B et al. Anatomy and physiology of subcutaneous adipose tissue by in vivo MRI and spectroscopy: Relationship with sex and presence of cellulite, *Skin Research and Technology*; 8: 118-124.
[iv]Zerini I et al. Cellulite treatment: a comprehensive literature review. *J Cosmet Dermatol*. 2015 Sep 14(3):224-40