



Phase 3 Data of Collagenase Clostridium Histolyticum for the Investigational Treatment of Cellulite to Be Presented at The Aesthetic Meeting 2019

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Clinical Investigator Dr. Lawrence Bass is a Featured Hot Topics Speaker

DUBLIN, May 17, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that clinical data from a Phase 3 investigational study of collagenase clostridium histolyticum (CCH) for the treatment of cellulite will be presented by Lawrence Bass, M.D., a board-certified plastic surgeon with a practice in New York City. Dr. Bass will present the Phase 3 data during the Premier Global Hot Topics session, which takes place today from 1:00pm – 6:00pm (Central Time) at the New Orleans Ernest N. Morial Convention Center. The Hot Topics session is considered to be a highlight of The Aesthetic Meeting 2019, the annual meeting of the American Society for Aesthetic Plastic Surgery (The Aesthetic Society).

"Last year at Hot Topics, my colleagues expressed great interest in the data that I presented on CCH for cellulite," said Dr. Bass. "An injectable option to treat cellulite, if approved, would be very meaningful to our patients, which is why I am thrilled to be back this year to share the positive results from the Phase 3 studies."

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.

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).

"As a Premier Partner of The Aesthetic Society, we could not be more pleased that our data is a Hot Topic at their annual meeting," said Matthew Davis, M.D., R.Ph., Endo's Senior Vice President and Chief Medical Officer. "We greatly appreciate investigators like Dr. Bass who have helped further our understanding of the potential for CCH by participating in these studies and presenting their scientific findings to their peers."

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 makes cellulite more noticeable, but it may be present even in thin subjects. Genetics may also play a role, since cellulite tends to run in families.

Despite multiple therapeutic approaches for the attempted treatment of patients with cellulite, there are currently no FDA-approved injectable treatments 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.

About The Aesthetic Society

[The American Society for Aesthetic Plastic Surgery \(The Aesthetic Society\)](#) is recognized as the world's leading organization devoted entirely to aesthetic plastic surgery and cosmetic medicine of the face and body. The Aesthetic Society is comprised of more than 2,600 members in North America and internationally; 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. All members worldwide adhere to a strict Code of Ethics and must meet stringent membership requirements. The Aesthetic Society is at the forefront of innovation in aesthetic plastic surgery and cosmetic medicine globally.

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 Bass, 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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