



Endo Aesthetics Data to be Featured in Five Presentations at the American Society for Dermatologic Surgery's Annual Meeting (ASDS)

October 9, 2020

DUBLIN, Oct. 9, 2020 /CNW/ -- Endo International plc (NASDAQ:ENDP) today announced that data relevant to the use of Endo Aesthetics' Qwo™ (collagenase clostridium histolyticum-aaes) for the treatment of moderate to severe cellulite in the buttocks of adult women will be featured during the American Society for Dermatologic Surgery's Annual Meeting (ASDS). These data will be highlighted in three posters and two oral presentations during the virtual meeting taking place October 9 – 11, 2020.



Oral Presentations

On Friday, October 9th a presentation titled "Results From a 1000+ Subject Survey Assessing Satisfaction With a Hypothetical 1-Point Improvement on the Validated Patient-Reported Photonumeric Cellulite Severity Scale (PR-PCSS) Analysis," will be given by Sabrina Fabi, M.D., a board-certified dermatologist in California. Dr. Fabi will share results from a study designed to determine if a 1-point improvement in PR-PCSS score is a clinically meaningful outcome and will highlight the importance of patient education during consultations.

On Sunday, October 11th, Melanie Palm, M.D., will present "Real-World Effectiveness and Safety of Collagenase Clostridium Histolyticum-aaes Injections for the Treatment of Thigh Cellulite in Women: An Interim Analysis". During this presentation, Dr. Palm, a board-certified dermatologist and cosmetic surgeon in California, will outline the 90-day findings from ongoing phase 3b REAL™ and PIXELS™ studies assessing not only investigator-perceived and patient-reported results at 90-days, but also the quantitative corroboration of these findings, with 3D-image scans.

Poster Presentations

All poster presentations will be available for ASDS attendees throughout the Congress.

- Title: Long-Term Durability of Collagenase Clostridium Histolyticum-aaes Treatment Effectiveness for Cellulite in Women
 - Authors: Joely Janette Kaufman, M.D., Vernon Leroy Young, M.D., Matthew Zook, M.D., Saji Vijayan, MBBS, D.Diab., Michael McLane PhD., Xiang Q Ph.D., Chajko KA, Lawrence Bass, M.D.
- Title: Patient Retention Strategies for Long-Term Extension Aesthetic Studies: Collagenase Clostridium Histolyticum-aaes (QWO™) Phase 3 Clinical Study Experience
 - Authors: Joely Janette Kaufman, M.D., James Clark M.D., Kappa Peddy, M.D., Alex Cazzaniga Ph.D., Davina Cupo, Robert Yon, Rosalie Filling
- Title: A Survey of Dermatology Healthcare Professional Knowledge, Perception, and Experience Regarding Cellulite and Its Treatment
 - Authors: Jill Edgecombe, Daniel Connolly, Sherry Chen, Stephanie Wenstrup

"We are pleased with the breadth and depth of the data that will be presented at the ASDS meeting," said Matthew Davis, M.D., R.Ph., Senior Vice President and Chief Medical Officer of Endo. "Endo Aesthetics is committed to offering aesthetic healthcare providers data not only on the safety and efficacy of QWO, but also on the real world implications of this treatment, including patient retention and perceptions, as we prepare for the product's launch in spring 2021."

INDICATION

QWO is indicated for the treatment of moderate to severe cellulite in the buttocks of adult women.

IMPORTANT SAFETY INFORMATION FOR QWO CONTRAINDICATIONS

QWO is contraindicated in patients with a history of hypersensitivity to collagenase or to any of the excipients or the presence of infection at the injection sites.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions including anaphylaxis have been reported with the use of collagenase clostridium histolyticum. If such a reaction occurs, further injection of QWO should be discontinued and appropriate medical therapy immediately instituted. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions.

Injection Site Bruising

In clinical trials, 84% of subjects treated with QWO experienced injection site bruising. Subjects with coagulation disorders or using anticoagulant or antiplatelet medications (except those taking ≤ 150 mg aspirin daily) were excluded from participating in Trials 1 and 2.

QWO should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet (except those taking ≤ 150 mg aspirin daily) or anticoagulant therapy.

Substitution of Collagenase Products

QWO must not be substituted with other injectable collagenase products. QWO is not intended for the treatment of Peyronie's Disease or Dupuytren's Contracture.

ADVERSE REACTIONS

In clinical trials, the most commonly reported adverse reactions in patients treated with QWO incidence $\geq 10\%$ were at the injection site: bruising, pain, nodule and pruritus.

Click for Full [Prescribing Information](#) for QWO.

About Cellulite

Cellulite is a localized alteration in the contour of the skin that has been reported in over 90 percent of post-pubertal females and affects women of all races and ethnicities.^{1,2} The presence of cellulite is associated with changes in dermal thickness and in the fat cells and connective tissue below the skin.³ A primary factor in the cause of the condition is the collagen containing septae which attach the skin to the underlying fascia layers.^{4,5} The septae tether the skin which, with additional contributing protrusions of subcutaneous fat, causes the surface dimpling characteristic of cellulite.^{6,7} These fibrous septae are oriented differently, with varying thickness in females than in males, which informs our understanding of cellulite as a gender-related condition.⁸ Cellulite clinically presents on the buttocks, thighs, lower abdomen and arms.

It is known that cellulite is different from generalized obesity.⁹ In generalized obesity, adipocytes undergo hypertrophy and hyperplasia that is not limited to the pelvis, thighs, and abdomen.² In areas of cellulite, characteristic large, metabolically stable adipocytes have physiologic and biochemical properties that differ from adipose tissue located elsewhere.¹⁰ An anatomical study in 2019 found that women have increased fat lobule height compared with men, which may also contribute to the mattress-like appearance seen as a result of the tension of the fibrous septae.^{8,10} Weight gain can make cellulite more noticeable, but cellulite may be present even in thin subjects.⁹

About Endo Aesthetics™ LLC

Endo Aesthetics is embarking on a mission devoted to pushing the boundaries of aesthetic artistry. Driven by world-class research and development, Endo Aesthetics is advancing solutions to address unmet needs beginning with the first FDA-approved injectable treatment for cellulite in the buttocks. Headquartered in Malvern, PA, Endo Aesthetics is an affiliate of Endo International plc (NASDAQ: ENDP). Learn more at www.endoaesthetics.com.

About Endo International plc

Endo International plc (NASDAQ: ENDP) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from a global team of passionate employees collaborating to bring the best treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Endo has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania. Learn more at www.endo.com or connect with us on [LinkedIn](#).

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 Dr. Davis as well as 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:

1. Hexsel DM, et al. Side-by-side comparison of areas with and without cellulite depressions using magnetic resonance imaging. *Dermatol Surg*. 2009;35(10):1471-7.

2. Khan MH, et al. Treatment of cellulite: Part I. Pathophysiology. *J Am Acad Dermatol*. 2010;62:361-70.
3. Querleux B, et al. Anatomy and physiology of subcutaneous adipose tissue by in vivo magnetic resonance imaging and spectroscopy: Relationships with sex and presence of cellulite. *Skin Res Technol*. 2002;8(2):118-24.
4. Zhang YZ, et al. *Appl Environ Microbiol*. 2015;81(18):6098-6107.
5. Rossi AM, Katz BE. *Dermatol Clin*. 2014;32(1):51-59.
6. Edkins TJ, et al. *Clin Vaccine Immunol*. 2012;19(4):562-569.
7. Kaplan FT. *Drugs Today (Barc)*. 2011;47(9):653-667.
8. Rudolph C, et al. Structural gender-dimorphism and the biomechanics of the gluteal subcutaneous tissue – Implications for the pathophysiology of cellulite. *Plast Reconstr Surg*. 2019;143(4):1077-86.
9. Avram MM. Cellulite: a review of its physiology and treatment. *J Cosmet Laser Ther*. 2005;7:1-5.
10. Pierard GE, et al. Cellulite: from standing fat herniation to hypodermal stretch marks. *Am J Dermatopathol*. 2000;22(1):34-7.

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