



## **Endo to Present Qwo™ (collagenase clostridium histolyticum-aaes) Data at Vegas Cosmetic Surgery & Aesthetic Dermatology (VCS)**

September 24, 2020

DUBLIN, Sept. 24, 2020 /CNW/ -- Endo International plc (NASDAQ:ENDP) today announced that it will present data relevant to the use of Qwo™ (collagenase clostridium histolyticum-aaes) for the treatment of moderate to severe cellulite in the buttocks of adult women during Vegas Cosmetic Surgery & Aesthetic Dermatology (VCS). This data will be highlighted in two oral presentations during the virtual VCS symposium taking place September 24 – 27, 2020.



On Thursday, September 24<sup>th</sup> a presentation titled "Injectable Cellulite Treatment," will be given by Michael Gold, M.D., F.A.A.D., a board-certified dermatologist in Nashville, TN. This presentation will include a general overview of collagenase clostridium histolyticum-aaes and will review data from the product's phase 3 pooled trial analyses.

On Saturday, September 26<sup>th</sup> Sachin M. Shridharani, M.D., F.A.C.S., will present "Injectable Cellulite Treatment - Collagenase Clostridium Histolyticum-aaes Effect on Tissue Histology." During this presentation, Dr. Shridharani, a board-certified plastic surgeon in New York, NY, will outline findings from two new histology studies that were designed to characterize QWO's subdermal impact and investigate the most frequently reported adverse event, injection site bruising.

The data being presented by Dr. Shridharani introduces Enzymatic Subcision and Remodeling™ (ESR™), which is thought to be a key component of collagenase clostridium histolyticum-aaes' mechanism of action. QWO breaks down the mature, collagen-rich septae which are one cause of cellulite dimples and stimulates the onset of new collagen for a smoother looking appearance<sup>1,2</sup>.

"We are pleased that these data will be presented at Vegas Cosmetic Surgery & Aesthetic Dermatology, and as we prepare to launch QWO in spring 2021, we are committed to ensuring aesthetic healthcare providers have continued access to relevant research on the product," said Matthew Davis, M.D., R.Ph., Senior Vice President and Chief Medical Officer of Endo.

### **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  $\leq 150$  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  $\leq 150$  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.<sup>3,4</sup> The presence of cellulite is associated with changes in dermal thickness and in the fat cells and connective tissue below the skin.<sup>5</sup> A primary factor in the cause of the condition is the collagen containing septae which attach the skin to the underlying fascia layers.<sup>6,7</sup> The septae tether the skin which, with additional contributing protrusions of subcutaneous fat, causes the surface dimpling characteristic of cellulite.<sup>8,9</sup> 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.<sup>10</sup> Cellulite clinically presents on the buttocks, thighs, lower abdomen and arms.

It is known that cellulite is different from generalized obesity.<sup>11</sup> In generalized obesity, adipocytes undergo hypertrophy and hyperplasia that is not limited to the pelvis, thighs, and abdomen.<sup>4</sup> In areas of cellulite, characteristic large, metabolically stable adipocytes have physiologic and biochemical properties that differ from adipose tissue located elsewhere.<sup>12</sup> 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.<sup>10,12</sup> Weight gain can make cellulite more noticeable, but cellulite may be present even in thin subjects.<sup>11</sup>

### 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](http://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](http://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 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. Qwo™ package insert. Malvern, PA Endo Aesthetics LLC
2. Shridharani, Sachin (2020, September). Injectable Cellulite Treatment - Collagenase Clostridium Histolyticum-aaes Effect on Tissue Histology. Presented at Vegas Cosmetic Surgery & Aesthetic Dermatology, virtual meeting.
3. 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.
4. Khan MH, et al. Treatment of cellulite: Part I. Pathophysiology. *J Am Acad Dermatol.* 2010;62:361-70.
5. 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.
6. Zhang YZ, et al. *Appl Environ Microbiol.* 2015;81(18):6098-6107.
7. Rossi AM, Katz BE. *Dermatol Clin.* 2014;32(1):51-59.
8. Edkins TJ, et al. *Clin Vaccine Immunol.* 2012;19(4):562-569.
9. Kaplan FT. *Drugs Today (Barc).* 2011;47(9):653-667.
10. 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.
11. Avram MM. Cellulite: a review of its physiology and treatment. *J Cosmet Laser Ther.* 2005;7:1-5.
12. Pierard GE, et al. Cellulite: from standing fat herniation to hypodermal stretch marks. *Am J Dermatopathol.* 2000;22(1):34-7.

[histolyticum-aaes-data-at-vegas-cosmetic-surgery--aesthetic-dermatology-vcs-301137088.html](http://histolyticum-aaes-data-at-vegas-cosmetic-surgery--aesthetic-dermatology-vcs-301137088.html)

SOURCE Endo International plc