



## Endo Announces Publication of Phase 3 Qwo® (collagenase clostridium histolyticum-aes) Data in Peer-Reviewed Dermatologic Surgery

April 13, 2021

DUBLIN, April 13, 2021 /CNW/ -- Endo International plc (NASDAQ: ENDP) today announced that Phase 3 data evaluating Qwo® (collagenase clostridium histolyticum-aes) for the treatment of moderate to severe cellulite in the buttocks of adult women was published in *Dermatologic Surgery*, the official journal of the American Society for Dermatologic Surgery. In addition to Phase 3 studies, the publication also includes a supplemental video that demonstrates the injection techniques for QWO.



The Phase 3 studies, conducted from February 2018 to September 2018, demonstrated that QWO provides a clinically meaningful improvement in the appearance of moderate to severe cellulite in the buttocks of adult women compared to placebo. QWO received FDA approval in July 2020 and is the first and only injectable treatment for moderate to severe cellulite in the buttocks of adult women.

"The data, from the largest cellulite studies ever conducted, provides further evidence that QWO may be an effective treatment for women with a variety of skin types who dislike the dimples on their buttocks," said Joely Kaufman-Janette, M.D., lead author, principal investigator and board-certified dermatologist at Skin Associates of South Florida.

The RELEASE-1 and RELEASE-2 Phase 3 studies, which were identically designed, randomized, double blinded and placebo-controlled, assessed the efficacy and safety of QWO for the treatment of cellulite in women. A greater percentage of the 843 women treated during the studies (QWO vs. placebo: RELEASE 1, n=210 vs n=213; RELEASE-2, n=214 vs n=206) met the primary endpoint of a composite 2-level response on a 5-point cellulite severity scale. Over half of the women treated with QWO in both studies met the secondary endpoint, a 1-level improvement in the patient reported assessment.

"The secondary endpoints in these studies reaffirm that many study participants and their doctors found that QWO delivered a clinically relevant improvement in the appearance of cellulite, and we are thrilled to have this data published in the peer-reviewed *Dermatologic Surgery* journal," said Ravi Tayi, M.D., M.P.H., Endo's Chief Medical Officer. "As we continue to train doctors on the use of QWO, we remain committed to sharing timely and relevant data with aesthetic healthcare practitioners."

### 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 with an 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>1,2</sup> The presence of cellulite is associated with changes in dermal thickness and in the fat cells and connective tissue below the skin.<sup>3</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>4,5</sup> The septae tether the skin which, with additional contributing protrusions of subcutaneous fat, causes the surface dimpling characteristic of cellulite.<sup>6,7</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>8</sup> Cellulite clinically presents on the buttocks, thighs, lower abdomen and arms.

It is known that cellulite is different from generalized obesity.<sup>9</sup> In generalized obesity, adipocytes undergo hypertrophy and hyperplasia that is not limited to the pelvis, thighs, and abdomen.<sup>2</sup> In areas of cellulite, characteristic large, metabolically stable adipocytes have physiologic and biochemical properties that differ from adipose tissue located elsewhere.<sup>10</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>8,10</sup> Weight gain can make cellulite more noticeable, but cellulite may be present even in thin subjects.<sup>9</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 Endo International plc (NASDAQ: ENDP) business. Learn more at [www.endoaesthetics.com](http://www.endoaesthetics.com).

## About Endo

Endo (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. Learn more at [www.endo.com](http://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 Drs. Kaufman-Janette and Tayi as well as other statements regarding research and development outcomes, efficacy, adverse reactions, market and product potential, product launch timing 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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[collagenase-clostridium-histolyticum-aes-data-in-peer-reviewed-dermatologic-surgery-301268131.html](https://doi.org/10.1007/s12010-012-0131-1)

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