Endo's Qwo® (collagenase clostridium histolyticum-aaes) Data Presented at the American Society for Dermatologic Surgery's Annual Meeting

November 22, 2021

DUBLIN, Nov. 22, 2021 /PRNewswire/ -- Endo International plc (NASDAQ:ENDP) announced today that data from clinical and non-clinical studies of Endo Aesthetics' Qwo® (collagenase clostridium histolyticum-aaes), which received FDA approval in July 2020 for the treatment of moderate to severe cellulite in the buttocks of adult women, were presented during the annual meeting of the American Society for Dermatologic Surgery (ASDS).

The data were highlighted in five oral presentations during the meeting, which took place virtually November 19-21, 2021.

- **New data:** Safety and Efficacy of Qwo® for Buttock Cellulite in Women With Skin of Color: a Pooled Analysis of Randomized, Placebo-Controlled Trials
  - Authors: Valerie D. Callender, M.D.; Jeanine B. Downie, M.D., Jill Edgecombe, B.S.; Qinfang Xiang, Ph.D.; Kadriye Ciftci, M.D., Ph.D.; Sabrina Guillen Fabi, M.D.
- Reduction in Dimple Volume in Women With Buttock Cellulite Treated With Qwo®
  - Authors: Lawrence S. Bass, M.D.; Michael P. McLane, Ph.D.; Elizabeth Rosenberg, FNP; Jill Edgecombe, B.S.; Saji Vijayan, M.B.B.S.; Qinfang Xiang, Ph.D.; Genzhou Liu, Ph.D.; Michael S. Kaminer, M.D.
- Enzymatic Subcision and Remodeling After Qwo® Subcutaneous Injection: A Porcine Tissue Histology Study
  - Authors: Sachin M. Shridharani, M.D.; Shannon R. Dalton, Ph.D.; Saji Vijayan, M.B.B.S.; Ashish C. Bhatia, M.D.
- Real-World Effectiveness and Safety of Qwo®: an Interim Analysis for the Treatment of Thigh Cellulite in Women
  - Authors: Melanie Palm, M.D., M.B.A.; John H. Joseph, M.D.; Deanne Mraz Robinson, M.D.; Ashish C. Bhatia, M.D.; Sachin M. Shridharani, M.D.; Steven H. Dayan, M.D.; Lisa Donofrio, M.D.; Jose R. Montes, M.D.; Genzhou Liu, Ph.D.; David Hernandez, M.D.; Saji Vijayan, M.B.B.S.; Jill Edgecombe, B.S.; Sabrina Guillen Fabi, M.D.
- Assessment of Selected Mitigation Treatments on Injection-Site Bruising After Qwo® Injection For Buttock Cellulite in Women: An Interim Analysis of a Collaborative, Phase 4, Open-Label Trial
  - Authors: Steven H. Dayan, M.D.; Brian S. Biesman, M.D.; Suzanne Kilmer, M.D.; Kadriye Ciftci, M.D., Ph.D.; Jill Edgecombe, B.S.; Genzhou Liu, Ph.D.; Michael P. McLane, Ph.D.; Brenda LaTowsky, M.D.

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

IMPORTANT SAFETY INFORMATION

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 ≥ 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
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. Endo Aesthetics is an Endo International plc (NASDAQ: ENDP) business. Learn more at www.endoaesthetics.com.

About Endo International plc
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 passionate team members around the globe 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 or connect with us on LinkedIn.

Forward-Looking Statements
Certain information in this press release may be considered "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, any statements relating to the potential progress, timing or results of clinical studies or trials, research and development outcomes, market potential or product potential, safety, efficacy, effectiveness or availability. All forward-looking statements in this press release reflect Endo's current expectations of future events based on information available to Endo as of the date of this press release. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Endo's expectations and projections, including with respect to the impact of any litigation, investigation or settlement proceeding on our financial statements, including our cash flows from operations; our ability to adjust to changing market conditions; our ability to attract and retain key personnel; our ability to maintain compliance with our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt and long-term corporate ratings (which could increase our cost of capital) and exposing us to potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries' outstanding indebtedness; our ability to incur additional borrowings under the covenants in our then-existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness; and/or a significant reduction in our short-term and long-term revenues and/or otherwise cause us to be unable to fund our operations and liquidity needs, such as future capital expenditures and payment of our indebtedness. The occurrence or possibility of any such result may cause us to pursue one or more significant corporate transactions or remedial measures, including on a preventative or proactive basis. Actions that may be evaluated or pursued could include reorganization or restructuring activities of all or a portion of our business, asset sales or other divestitures, cost-saving initiatives or other corporate realignments, seeking strategic partnerships and exiting certain product or geographic markets. Some of these measures could take significant time to implement and others may require judicial or other third party approval. Any such actions may be complex, could entail significant costs and charges or could otherwise negatively impact shareholder value, and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all, or that they will result in their intended benefits. Other risks and uncertainties include general industry and market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development and regulatory processes, including regulatory decisions, product recalls, withdrawals and other unusual items; challenges related to product marketing, such as the unpredictability of market acceptance for new products and/or the acceptance of new indications for such products; inconsistency of treatment results among patients; potential difficulties in manufacturing; general economic conditions; and governmental laws and regulations affecting domestic and foreign operations. Endo expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Additional information concerning these and other risk factors can be found in Endo's periodic reports filed with the U.S. Securities and Exchange Commission and in Canada on the System for Electronic Data Analysis and Retrieval, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K.

References:

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