



Endo Aesthetics to Introduce New Clinical Study of Qwo® (collagenase clostridium histolyticum-aaes) at the Annual SCALE Meeting

May 5, 2022

DUBLIN, May 5, 2022 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced the upcoming launch of a new clinical study relevant to the use of Qwo® (collagenase clostridium histolyticum-aaes) for the treatment of moderate to severe cellulite in the buttocks of adult women. The design of the study will be featured during the annual **Symposium for Cosmetic Advances & Laser Education (SCALE)** multidisciplinary aesthetic medicine meeting, taking place in Nashville, TN, May 11-15, 2022.



The poster presentation, titled "APHRODITE-1: A Phase 2 Study of Different Interventions to Reduce Bruising Following Collagenase Clostridium Histolyticum-aaes Treatment for Cellulite of the Buttocks in Women," will share the objectives and unique design of this multi-cohort study which will test different interventions to assess their potential impact on reduction of bruising. The study has been created with the flexibility to add cohorts in order to test additional interventions over time if desired.

"I appreciate Endo's continued investment in research and development," said Joely Kaufman-Janette, M.D., lead author, principal investigator and board-certified dermatologist. "My patients who are bothered by their cellulite are excited about QWO. This new study, as well as future research, may have the potential to enhance their experience."

"We look forward to launching this study later this quarter and are committed to continuing to offer aesthetic healthcare providers data not only on the safety and efficacy of QWO, but also on the real-world experiences with this treatment," said James P. Tursi, M.D., Executive Vice President, Global Research & Development at Endo.

All poster presentations will be available for SCALE attendees live at the meeting and will be published on the [SCALE](#) website once the meeting concludes.

WHAT IS QWO®?

QWO is a prescription medicine used to treat moderate to severe cellulite in the buttocks of adult women.

IMPORTANT SAFETY INFORMATION

Do not receive QWO if you: are allergic to collagenase or to any of the ingredients in QWO, or have an active infection at the treatment area.

QWO may cause serious side effects, including:

- **Allergic (hypersensitivity) reactions, including anaphylaxis.** Call your healthcare provider right away if you have hives, trouble breathing, low blood pressure, swollen face, chest pain, dizziness or fainting after receiving QWO;
- **Injection site bruising**

Before receiving QWO, tell your healthcare provider if you:

- have a bleeding problem.
- are pregnant or may become pregnant, nursing or plan to nurse. You and your healthcare provider should decide if you will receive QWO or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. **Especially tell your healthcare provider if you take** a medicine that prevents the clotting of your blood (antiplatelet or anticoagulant).

The **most common side effects of QWO include:** injection site bruising, pain, areas of hardness, itching, redness, discoloration, swelling and warmth in the treatment area.

These are not all the possible side effects of QWO. Call your healthcare provider for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA at www.fda.gov/medwatch or 1-800-FDA-1088

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

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} A primary factor in the cause of the condition is the collagen-containing septae which attach the skin to the underlying fascia layers.^{3,4} The septae tether the skin which, with additional contributing protrusions of subcutaneous fat, causes the surface dimpling characteristic of cellulite.^{5,6} 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.⁷ Cellulite clinically presents on the buttocks, thighs, lower abdomen and arms.

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

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, the statements by Drs. Kaufman-Janette and Tursi and any statements relating to clinical trials, future research, timelines or expectations. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this press release reflect Endo's current expectations of future events based on existing trends and information and represent Endo's judgment only as of the date of this press release. Actual results may differ materially and adversely from current expectations based on a number of factors affecting Endo's businesses, including, among other things, the following: the outcome of our strategic review, contingency planning and any potential restructuring; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust matters; actual or contingent liabilities; settlement discussions or negotiations; the impact of competition including loss of exclusivity and generic competition; our ability to satisfy judgments or settlements or to pursue appeals including bonding requirements; our ability to adjust to changing market conditions; our inability to maintain compliance with financial covenants and operating obligations which would expose us to potential events of default under our outstanding indebtedness; our ability to incur additional debt or refinance our outstanding indebtedness; a significant reduction in our short-term or long-term revenues which could cause us to be unable to fund our operations and liquidity needs; the performance of Qwo®, including consumer and physician acceptance; the impact that known and unknown side effects may have on market perception and consumer preference; the effectiveness of advertising and other promotional campaigns; unfavorable publicity regarding the misuse of opioids; and our ability to develop our product pipeline and to continue to develop the market for Qwo® and other products. The occurrence or possibility of any such result has caused us to engage, and may result in further engagement in strategic reviews that ultimately may result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. Those remedial measures could include a potential corporate reorganization, restructuring or bankruptcy filing involving all or a portion of our business, asset sales or other divestitures, cost-saving initiatives, corporate realignments or strategic partnerships. 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. Therefore, the reader is cautioned not to rely on these forward-looking statements. Endo expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law. Additional information concerning risk factors, including those referenced above, can be found in press releases issued by Endo, as well as Endo's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in Endo's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

References

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