Endo to Cease Production and Sale of Qwo® (collagenase clostridium histolyticum-aaes)

December 6, 2022

DUBLIN, Dec. 6, 2022 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that it will cease the production and sale of Endo Aesthetics' Qwo® (collagenase clostridium histolyticum-aaes) in light of market concerns about the extent and variability of bruising following initial treatment as well as the potential for prolonged skin discoloration.

For more than a year, Endo worked to address those concerns, including launching an open-label study in June 2022, APHRODITE, to test different interventions and whether they might mitigate bruising. Although certain APHRODITE study cohorts' results reflected a modest reduction of bruising area and severity, none achieved a consistent level of reduced bruising following initial treatment to adequately alleviate the market's concerns.

"After careful consideration, we have determined that QWO does not represent a viable commercial opportunity for Endo," said Blaise Coleman, President and CEO of Endo. "This difficult decision unfortunately results in a workforce reduction. We are grateful for the dedication and hard work of all team members who supported QWO and our Endo Aesthetics business, and we are committed to providing support and assistance to our impacted team members."

This decision is expected to result in annualized pre-tax cash savings of approximately $50 million to $60 million and a reduction to Endo's global workforce of approximately 90 full-time positions. In connection with ceasing QWO production and sales, the Company expects to incur pre-tax cash restructuring charges of approximately $15 million to $20 million and record a total pre-tax restructuring charge of approximately $235 million to $250 million in the fourth quarter 2022. The Company will seek any necessary approvals from the United States Bankruptcy Court for the Southern District of New York in connection with this decision.

QWO remains an FDA-approved product with clinically proven results and an established safety profile, so practices may continue to use unexpired QWO that they have in stock, as well as order additional supply. Alternatively, practitioners can return unused QWO purchased prior to this announcement for a refund. Practices will be notified about these options.

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 with an incidence ≥ 10% were at the injection site: bruising, pain, nodule and pruritus.

Click for Full Prescribing Information for QWO.

About Endo
Endo (OTC: ENDPQ) 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 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.

Cautionary Note Regarding 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 Mr. Coleman and any statements related to the Company's efforts to expand and enhance its portfolio or the decision to cease production and sale of QWO, including any estimated expenses, charges, costs or savings, and any other statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the Company's strategy; risks and uncertainties associated with chapter 11 proceedings; the negative impacts on the Company's businesses as a result of filing for and operating under chapter 11 protection; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results while in chapter 11 proceedings; the Company's ability to discharge claims in chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; and risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in chapter 11 proceedings. The Company 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 the Company, as well as the Company'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 the Company'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. Copies of the Company's press releases and additional information about the Company are available at www.endo.com or you can contact the Company's Investor Relations Department at relations.investor@endo.com.

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