Endo Announces Submission of Biologics License Application to FDA for Collagenase Clostridium Histolyticum (CCH) in Patients with Cellulite

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DUBLIN, Sept. 6, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) announced today that the Company has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for collagenase clostridium histolyticum (CCH) for the treatment of cellulite in the buttocks. The submission is based on positive results from two identical Phase 3 RELEASE* studies that were were presented at the 2019 Annual Meeting of the American Academy of Dermatology (AAD) in Washington, DC and subsequently at the The Aesthetic Meeting 2019 in New Orleans, LA.

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 CCH for the treatment of cellulite in women. A greater percentage of the 843 women treated during the studies (CCH vs. placebo: RELEASE 1, n=210 vs n=213; RELEASE-2, n=214 vs n=206) met the primary endpoint of response with CCH versus placebo in both the RELEASE-1 (P=0.006) and RELEASE-2 (P=0.002) studies.

In addition, statistically significant improvements with CCH versus placebo were observed for 8 of 8 (RELEASE-1) and 7 of 8 (RELEASE-2) secondary endpoints. All patient-centric endpoints, evaluated using validated patient-reported scales like Patient Reported Photonumeric Cellulite Severity Scale (PR-PCSS), Subject Global Aesthetic Improvement Scale (S-GAIS), Patient Reported Cellulite Impact Score (PR-CIS) and Subject Self Rating Scale (SSRS), showed statistically significant improvement in the CCH group when compared to the placebo group. Most adverse events observed in CCH-treated patients were transient, mild/moderate and injection-site related (e.g., bruising, pain, induration, pruritus, erythema, and discoloration).

The FDA has a 60-day filing review period to determine whether the BLA is complete and acceptable for filing. Endo will communicate the FDA's decision.

About Cellulite
Cellulite is a localized alteration in the contour of the skin that has been reported in 85 to 98 percent of post-pubertal females and affects women of all races and ethnicities.[1,2] The primary cause of the condition is a thickening of the collagen septae that attach the skin to the underlying fascia layers with additional contributing protrusions of subcutaneous fat. The septae tether the skin, which causes the surface dimpling characteristic of cellulite.[2,3] Cellulite clinically presents on the buttocks, thighs, lower abdomen and arms.

It is known that cellulite is different from generalized obesity. In generalized obesity, adipocytes undergo hypertrophy and hyperplasia that are not limited to the pelvis, thighs, and abdomen.[4] In areas of cellulite, characteristic large, metabolically stable adipocytes have physiologic and biochemical properties that differ from adipose tissue located elsewhere. Weight gain makes cellulite more noticeable, but it may be present even in thin subjects. Genetics may also play a role, since cellulite tends to run in families.

Despite multiple therapeutic approaches for the attempted treatment of patients with cellulite, there are currently no FDA-approved injectable treatments on the market.[5]

About Endo International plc
Endo International plc (NASDAQ: ENDP) is a highly-focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

Forward Looking Statements
This press release may contain certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation, including statements regarding research and development outcomes, regulatory, marketing and reimbursement approvals, 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 as well as the risks that the FDA will accept the BLA submitted for CCH, whether and when the BLA or any such other applications may be approved by the FDA and the general unpredictability of the regulatory process. 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.

*__R__andomized __E__va__L__uation of C__E__llulite Reduction by Coll__A__gena__SE__ Clostridium Histolyticum (RELEASE)

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