Endo Announces Publication Of Collagenase Clostridium Histolyticum (CCH) Phase 2 Data In Dermatologic Surgery

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Leading Peer-Reviewed Dermatology Journal Features Phase 2 Data

DUBLIN, March 19, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced the publication of Phase 2 data evaluating collagenase clostridium histolyticum (or "CCH") for the treatment of cellulite in *Dermatologic Surgery,* the official journal of the American Society for Dermatologic Surgery. CCH is the first and only investigational injectable treatment designed specifically to reduce the appearance of cellulite by disrupting the collagen structure of fibrous septae, which cause dimpling of the skin.

Consistent with the recently released Phase 3 studies, the Phase 2 data recently published in the journal online, demonstrate that CCH delivered a clinically meaningful and statistically significant improvement as compared to placebo for all primary and secondary endpoints.

"The possibility of an injectable treatment for cellulite is exciting for both patients and aesthetic physicians," said Dr. Neil Sadick, lead investigator and Clinical Professor of Dermatology, Weill Cornell Medical College. "As the clinical trial program for CCH advances, each new study and its corresponding data analysis demonstrate that CCH could be a major advancement in treating an issue that affects a majority of women during their lifetime."

The Phase 2 clinical trial enrolled 375 women aged 18 years or older in the United States who were randomized to receive up to three treatment sessions of CCH (0.84 mg/session) or placebo, with each treatment session occurring approximately 21 days apart. Twelve injections were administered into cellulite dimples during each session across an entire treatment area – left or right buttock, or left or right posterior thigh. A significant percentage (CR-PCSS = 54.2% improvement; PR-PCSS = 72.3% improvement) of trial subjects receiving CCH achieved at least a 1-point improvement of cellulite severity. CCH was well-tolerated in the treated subjects with most adverse events being mild to moderate in severity, and primarily limited to the local injection area (e.g. bruising, pain, nodule, pruritus, erythema, and discoloration).

"The results of this study add to the evidence that CCH, if approved, can play a significant role in reducing the appearance of cellulite," said Matthew Davis, M.D., R.Ph., Endo's Senior Vice President and Chief Medical Officer. "The Phase 2 and Phase 3 data continue to substantiate our ongoing efforts to develop an injectable treatment for cellulite."

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 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 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 statement by Drs. Davis and Sadick, and other statements regarding research and development outcomes, 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. 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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Media: Heather Zoumas-Lubeski, (484) 216-6829; Investors: Pravesh Khandelwal, (845) 364-4833