Endo Announces FDA's Acceptance of Original Biologics License Application (BLA) for Collagenase Clostridium Histolyticum (CCH) in Patients with Cellulite

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DUBLIN, Nov. 19, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the original Biologics License Application (BLA) for collagenase clostridium histolyticum (CCH) for the treatment of cellulite in the buttocks. The Prescription Drug User Fee Act (PDUFA), or target action date for the BLA, has been set for July 6, 2020.

"We have confidence in and are excited by the promising results of our CCH for cellulite program, which encompasses the largest U.S. clinical trials for the treatment of cellulite in history[1]," said Paul Campanelli, Endo's Chairman, President and Chief Executive Officer. "Acceptance of our BLA is a significant milestone and we look forward to advancing the next steps to bring this treatment to aesthetic physicians and their patients."

The BLA is supported by the results of the RELEASE*-1 and RELEASE-2 Phase 3 studies, as well as a robust clinical and pre-clinical program.

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.[2,3] 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.[3,4] 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.[5] 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.[6]

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 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 statements by Mr. Campanelli, and other statements regarding FDA's review process, timing and results, 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.

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

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