



Endo Presents Data on the Use of a Standing MRI for the Evaluation of Cellulite at the American Society for Dermatologic Surgery (ASDS) Annual Meeting

October 24, 2019

DUBLIN, Oct. 24, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that it will present data on the use of a standing MRI as compared to prone MRI for the evaluation of cellulite at the upcoming Annual Meeting of the American Society for Dermatologic Surgery (ASDS) in Chicago, IL. Endo will display two posters from October 24th until October 27th. The first poster will present a case study comparison of the use of a standing MRI versus a prone MRI for the evaluation of cellulite. The second poster will be an encore presentation of the Phase 3 data of collagenase clostridium histolyticum (CCH) for the investigational treatment of cellulite.

The first abstract poster will be titled "**The First Reported Use of Standing MRI for the Evaluation of Cellulite: A Case Study Comparison of Standing vs. Standard (Prone) MRI.**" This case study was designed to compare the anatomy of collagen septae in a woman with cellulite using a standing MRI versus standard (prone) MRI, because cellulite is typically observed in an upright/standing position. Such comparison results showed a <10° difference between the angle of collagen septae orientation relative to the dermis in the standing and prone MRI. Septae orientation in the prone position was not perpendicular to the skin.

The second abstract poster, titled "**Two Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trials of Collagenase Clostridium Histolyticum (CCH) for the Treatment of Cellulite,**" includes data previously presented at the 2019 Aesthetic Society meeting, on May 17, 2019. The RELEASE-1 and RELEASE-2 Phase 3 studies, which were identically designed, randomized, double-blinded and placebo-controlled, assessed the efficacy, safety and tolerability 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. 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).

"We are pleased that the data from these studies will be presented at the premier meeting for dermatologic surgeons," said Matthew Davis, M.D., R.Ph., Chief Medical Officer, Senior Vice President, Research and Development, Branded Pharmaceuticals at Endo Pharmaceuticals. "It is important that aesthetic healthcare providers have data on the most effective ways to evaluate the internal structure of cellulite. We believe our continued research will improve potential outcomes and patient satisfaction with cellulite treatments that target collagen septae."

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.

About the American Society for Dermatologic Surgery (ASDS)

The American Society for Dermatologic Surgery (ASDS) is the largest specialty organization exclusively representing dermatologic surgeons who have unique training and experience to treat the health, function and beauty of your skin. ASDS members are pioneers in the field. Many are involved in the clinical studies that bring popular treatments to revitalize skin and fill and diminish wrinkles to the forefront. Their work has helped create and enhance many of the devices that remove blemishes, hair and fat, and tighten skin. Dermatologic surgeons also are experts in skin cancer prevention, detection and treatment. As the incidence of skin cancer rises, dermatologic surgeons are committed to taking steps to minimize the life-threatening effects of this disease. For more information, visit asds.net.


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 Dr. Davis, 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

1. Avram M. Cellulite: a review of its physiology and treatment, *Journal of Cosmetic Laser Therapy* 2004; 6: 181–185.
2. Khan MH et al. Treatment of cellulite: Part I. Pathophysiology. *J Am Acad Dermatol.* 2010 Mar;62(3):361-70.
3. Querleux B et al. Anatomy and physiology of subcutaneous adipose tissue by in vivo MRI and spectroscopy: Relationship with sex and presence of cellulite, *Skin Research and Technology*; 8: 118-124.
4. Khan MH, Victor F, Rao B, Sadick NS. Treatment of cellulite: Part I. Pathophysiology. *J Am Acad Dermatol* 2010;62(3):361-370.
5. Zerini I et al. Cellulite treatment: a comprehensive literature review. *J Cosmet Dermatol.* 2015 Sep 14(3):224-40

 View original content: <http://www.prnewswire.com/news-releases/endo-presents-data-on-the-use-of-a-standing-mri-for-the-evaluation-of-cellulite-at-the-american-society-for-dermatologic-surgery-asds-annual-meeting-300943323.html>

SOURCE Endo International plc

Media: Heather Zoumas-Lubeski, (484) 216-6829, media.relations@endo.com; Investors: Pravesh Khandelwal, (845) 364-4833, relations.investor@endo.com