



Endo Presents New XIAFLEX® (collagenase clostridium histolyticum) Data at the 2019 Fall Meeting of the Sexual Medicine Society of North America (SMSNA)

October 25, 2019

DUBLIN, Oct. 25, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that five new studies of XIAFLEX® (collagenase clostridium histolyticum) for the treatment of Peyronie's disease will be presented as poster presentations at the 20th Annual Fall Meeting of the Sexual Medicine Society of North America (SMSNA) in Nashville, TN, October 24 – 27, 2019. One of the studies will also be presented as a Moderated (Oral) Poster Presentation on October 25. The studies are available on the SMSNA meeting website at <http://www.smsna.org/V1/meetings/20th-annual-fall-scientific-meeting-of-smsna/program/scientific-program>.

"These new analyses continue to support the potential of Peyronie's disease treatment with XIAFLEX®, the first and only therapy approved by the U.S. Food and Drug Administration (FDA) to treat this intimate condition," said Matthew Davis, M.D., R.Ph., Endo's Senior Vice President and Chief Medical Officer. "We are encouraged by these findings and we are committed to educating physicians and patients about possible outcomes for Peyronie's disease treatments."

XIAFLEX® data to be presented include:

- Penile Surgery is Associated with a Higher Rate of Penile Complications and Pain Medication Use Compared to Collagenase Clostridium Histolyticum in Patients with Peyronie's Disease (Abstract #158) **(Moderated (Oral) Poster Presentation)**
- Therapeutic Trends in the Management of Patients with Peyronie's Disease (Abstract #352) **(Moderated E-Poster)**
- Likelihood of Subsequent Penile Surgery for Patients with Peyronie's Disease Previously Treated with Collagenase Clostridium Histolyticum or Penile Surgery (Abstract #384) **(Moderated E-Poster)**
- Long-term Curvature Deformity Characterization in Patients Previously Treated With Collagenase Clostridium Histolyticum for Peyronie's Disease by Plaque Calcification (Abstract #350) **(Moderated E-Poster)**
- Retrospective Claims Analysis of Patients' Characteristics Affecting the Choice of Treatment Among Patients with Peyronie's Disease (Abstract #348) **(Moderated E-Poster)**

XIAFLEX® PD Professional Indication and Important Safety Information

Indication

XIAFLEX® is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

Important Safety Information for XIAFLEX®

WARNING: CORPORAL RUPTURE (PENILE FRACTURE) OR OTHER SERIOUS PENILE INJURY IN THE TREATMENT OF PEYRONIE'S DISEASE

Corporal rupture (penile fracture) was reported as an adverse reaction in 5 of 1044 (0.5%) XIAFLEX®-treated patients in clinical studies. In other XIAFLEX®-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded.

Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 (3.7%) XIAFLEX®-treated patients.

Signs or symptoms that may reflect serious penile injury should be promptly evaluated to assess for corporal rupture or severe penile hematoma which may require surgical intervention.

Because of the risks of corporal rupture or other serious penile injury, XIAFLEX® is available for the treatment of Peyronie's disease only through a restricted program under a

Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX® REMS Program.

- XIAFLEX® is contraindicated in the treatment of Peyronie's plaques that involve the penile urethra due to potential risk to this structure and in patients with a history of hypersensitivity to XIAFLEX® or to collagenase used in any other therapeutic application or application method
- Injection of XIAFLEX® into collagen-containing structures such as the corpora cavernosa of the penis may result in damage to those structures and possible injury such as corporal rupture (penile fracture). Therefore, XIAFLEX® should be injected only into the Peyronie's plaque and care should be taken to avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis
- In the double-blind, placebo-controlled portions of the clinical trials in Peyronie's disease, a greater proportion of XIAFLEX®-treated patients (4%) compared to placebo-treated patients (1%) had localized pruritus after up to 4 treatment cycles (involving up to 8 XIAFLEX® injection procedures). The incidence of XIAFLEX®-associated pruritus was similar after each injection regardless of the number of injections administered

- Because XIAFLEX[®] contains foreign proteins, severe allergic reactions to XIAFLEX[®] can occur. Anaphylaxis was reported in a post-marketing clinical trial in one patient who had previous exposure to XIAFLEX[®] for the treatment of Dupuytren's contracture. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX[®] injections. The safety of more than one treatment course of XIAFLEX[®] is not known
- In the XIAFLEX[®] controlled trials in Peyronie's disease, 65.5% of XIAFLEX[®]-treated patients developed penile hematoma, and 14.5% developed penile ecchymosis. Patients with abnormal coagulation (except for patients taking low-dose aspirin, eg, up to 150 mg per day) were excluded from participating in these studies. Therefore, the efficacy and safety of XIAFLEX[®] in patients receiving anticoagulant medications (other than low-dose aspirin, eg, up to 150 mg per day) within 7 days prior to XIAFLEX[®] administration is not known. In addition, it is recommended to avoid use of XIAFLEX[®] in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin)
- In the XIAFLEX[®] clinical trials for Peyronie's disease, the most frequently reported adverse drug reactions (≥25%) and at an incidence greater than placebo included: penile hematoma, penile swelling, and penile pain


Please see the accompanying [full Prescribing Information, including Boxed Warning and Medication Guide](#).

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 applicable Canadian securities legislation, including the statements by Dr. Davis and 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. 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.

 View original content: <http://www.prnewswire.com/news-releases/endo-presents-new-xiaflex-collagenase-clostridium-histolyticum-data-at-the-2019-fall-meeting-of-the-sexual-medicine-society-of-north-america-smsna-300944085.html>

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