Endo to Present New XIAFLEX® (collagenase clostridium histolyticum) Data at the 2019 American Society for Surgery of the Hand's (ASSH) Annual Meeting

September 5, 2019

DUBLIN, Sept. 5, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that four new studies of XIAFLEX®(collagenase clostridium histolyticum), including real-world data, for the treatment of Dupuytren's contracture will be presented as ePosters at the 74th Annual Meeting of the American Society for Surgery of the Hand (ASSH) in Las Vegas, Nevada, September 5 - 7, 2019. The studies are available on the ASSH meeting website at https://epostersonline.com/assh2019.

"These new insights reinforce our commitment to supporting the Dupuytren's contracture community by shedding light on real-world treatment implications," said Matthew Davis, M.D., R.Ph., Endo's Senior Vice President and Chief Medical Officer. "Physicians have several options for treating Dupuytren's contracture and we hope that this data will encourage them to discuss all options with their patients, including nonsurgical treatments like XIAFLEX®."

XIAFLEX® data to be presented include:

- Productivity Loss and Indirect Costs of Patients with Dupuytren Contracture Treated With Collagenase Clostridium Histolyticum or Fasciectomy: A Retrospective Claims Analysis During a 5-year Period (2012-2016) (Abstract #1233; Poster #143)
- Return to Function in Adults with Dupuytren Contracture Treated with Collagenase Clostridium Histolyticum Versus Fasciectomy (Abstract #1549; Poster #144)
- US Healthcare Costs and Resource Use for privately Insured Patients with Dupuytren's Contracture Treated with Collagenase Clostridium Histolyticum Versus Fasciectomy (Abstract #1573; Poster #145)
- Incidence of Tendon Rupture After Collagenase Clostridium Histolyticum Injection for Treatment of Dupuytren Contracture in Adults: A Postmarketing Safety Analysis (Abstract #1610; Poster #264)

XIAFLEX® DC HCP Indication and Important Safety Information

INDICATION
XIAFLEX® is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.

IMPORTANT SAFETY INFORMATION FOR XIAFLEX®

- XIAFLEX® is contraindicated in patients with a history of hypersensitivity to XIAFLEX® or to collagenase used in any other therapeutic application or application method
- In the controlled and uncontrolled portions of clinical trials in Dupuytren's contracture, flexor tendon ruptures occurred after XIAFLEX® injection. Injection of XIAFLEX® into collagen-containing structures such as tendons or ligaments of the hand may result in damage to those structures and possible permanent injury such as tendon rupture or ligament damage. Therefore, XIAFLEX® should be injected only into the collagen cord with a MP or PIP joint contracture, and care should be taken to avoid injecting into tendons, nerves, blood vessels, or other collagen-containing structures of the hand. When injecting a cord affecting a PIP joint of the fifth finger, the needle insertion should not be more than 2 to 3 mm in depth and avoid injecting more than 4 mm distal to the palmar digital crease
- Other XIAFLEX®-associated serious local adverse reactions in the controlled and uncontrolled portions of the studies included pulley rupture, ligament injury, complex regional pain syndrome (CRPS), sensory abnormality of the hand, and skin laceration (tear). In a historically controlled post-marketing trial, the incidence of skin laceration (22%) was higher for subjects treated with two concurrent injections of XIAFLEX® compared with subjects treated with up to three single injections in the placebo-controlled premarketing trials (9%). Cases of skin laceration requiring skin graft after finger extension procedures have been reported post-marketing. Signs or symptoms that may reflect serious injury to the injected finger/hand should be promptly evaluated because surgical intervention may be required.
- In the controlled portions of the clinical trials in Dupuytren's contracture, a greater proportion of XIAFLEX®-treated patients (15%) compared to placebo-treated patients (1%) had mild allergic reactions (pruritus) after up to 3 injections. The incidence of XIAFLEX®-associated pruritus increased after more XIAFLEX® injections in patients with Dupuytren's contracture
- Because XIAFLEX® contains foreign proteins, severe allergic reactions to XIAFLEX® can occur. Anaphylaxis was reported in a post-marketing clinical study 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.
- In the XIAFLEX® trials in Dupuytren's contracture, 70% and 38% of XIAFLEX®-treated patients developed an

ecchymosis/contusion or an injection site hemorrhage, respectively. 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 Dupuytren's contracture, the most common adverse reactions reported in ≥25% of patients treated with XIAFLEX® and at an incidence greater than placebo were edema peripheral (eg, swelling of the injected hand), contusion, injection site hemorrhage, injection site reaction, and pain in the injected extremity

Please see the accompanying full Prescribing Information, including 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 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.

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