Endo Announces Five Presentations at the Sexual Medicine Society of North America (SMSNA) Annual Meeting

November 16, 2023

DUBLIN, Nov. 16, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that five new presentations related to Peyronie's disease, or PD, and XIAFLEX® (collagenase clostridium histolyticum, or CCH, injection 0.9 mg) will be shared during the Sexual Medicine Society of North America (SMSNA) annual meeting, taking place November 16-19 in San Diego.

"The relatively common condition of Peyronie's disease—estimated to affect 1 in 10 men in the U.S.—remains under-studied and is often misunderstood," said Dr. Jesse Mills, urologist and presenter of the data analysis poster. "Efforts like the post hoc analysis of XIAFLEX® Phase 3 data and the new landmark registry aim to advance medical knowledge of PD and support patient outcomes."

The five new Endo-sponsored and Endo-supported presentations are below:

- Peyronie's Disease Patients with Penile Pain at Baseline Treated with Collagenase Clostridium Histolyticum: A Post Hoc Analysis
    - Authors: Jesse N. Mills, MD; Gregory A. Broderick, MD; Gregory J. Kaufman, MD; James P. Tursi, MD; Marian Ayad, PharmD BCPS; Tina Rezakhani, PharmD MBA; Jeffrey Andrews, MS; Sajel Patel, PharmD; Landon Trost, MD
    - Sponsored by Endo
- Clinical Understanding through Real-world data to Validate Effectiveness of treatments in Peyronie's Disease (CURVE-PD): Registry Design
    - Authors: Jill Davis, MS; Jesse N. Mills, MD; Joshua Henderson; Marc Mason; Angel Cronin; Femida Gwadry-Sridhar, BSc Pharm, MSc (Epi), PhD; David Hurley, MD; Greg Kaufman, MD; Ranjith Ramasamy, MD; Mohit Khera, MD
    - Sponsored by Endo
- Outcomes of Collagenase Clostridium Histolyticum in Men with Ventral Curvatures: An Updated Series
    - Authors: Henry Larson, BSN; Joshua Savage, PA-C; Klinton Brearton, CNP; Riley Warner, PA-C; Matthew Ziegelmann, MD; Tobias Kohler, MD; Landon Trost, MD
    - Publication grant provided by Endo
- Efficacy of a Novel Collagenase Clostridium Histolyticum Protocol for Peyronie's Disease Among Prior Non-responders: A Randomized, Controlled, Single-Blinded Study
    - Authors: Bryce Palmer, BS; Joshua Savage, PA-C; Klinton Brearton, CNP; Riley Warner, PA-C; Matthew Ziegelmann, MD; Sevann Helo, MD; Tobias Kohler, MD; Landon Trost, MD
    - Investigator-initiated research grant provided by Endo
- Comparison of Collagenase Clostridium Histolyticum to Surgery for the Management of Peyronie's Disease: A Randomized Trial – 1 Year Outcomes
    - Authors: Henry Larson, BSN; Joshua Savage, PA-C; Klinton Brearton, CNP; Riley Warner, PA-C; Matthew Ziegelmann, MD; Sevann Helo, MD; Tobias Kohler, MD; Landon Trost, MD
    - Investigator-initiated research grant provided by Endo

About the Post Hoc Phase 3 Data Analysis[1]

A post hoc analysis of pooled data from two randomized, double-blind, placebo-controlled Phase 3 trials was conducted to evaluate CCH treatment and improvement in penile curvature in participants presenting with/without penile pain at baseline and disease duration of 12–18 months or >18 months.

CCH-treated participants were stratified by the reporting of moderate-severe pain or no pain at baseline. Additional subgroup analyses stratified participants by presence of pain and disease duration (12–18 or >18 months). The primary efficacy endpoint was the percentage change in penile curvature at week 52 from baseline.

Data support that there were no clear differences in CCH treatment outcomes between participants experiencing moderate-severe pain or no pain at baseline regardless of disease duration (12–18 versus >18 months). These analyses are consistent with other literature evaluating the efficacy of CCH in the acute phase of disease and suggest that ongoing pain is not a contraindication to CCH therapy.

About the CURVE-PD Registry
CURVE-PD (NCT05873595) is a non-interventional study of up to 1,000 PD patients from 15 sites who have initiated treatment within two weeks before, at or any time after the date of enrollment. Patients will be followed for up to one year, and data will be collected from the patients, their healthcare providers and their partners.

Patients will answer questions related to, but not limited to, reasons for treatment choice, self-measurement of curve before and after treatments; ability to participate in sexual activities before and after treatment; in-home stretching/modeling to complement in-office procedures; satisfaction, depression and anxiety scales, including the Peyronie's Disease Questionnaire (PDQ); and patient and partner satisfaction.

Healthcare providers will answer questions related to, but not limited to, reasons for treatment choice, details of treatment, length and curve of penis before and after treatment and location of plaque treated.

This registry will create the largest and most comprehensive collection of real-world PD data on treatment outcomes.

About Peyronie's Disease
Peyronie's disease (PD) is a condition in which a buildup of fibrous scar tissue causes a curvature deformity of the penis. This curvature can be painful during arousal and intimacy.[3] It is estimated that PD can affect as many as 1 in 10 men in the U.S.,[4] but diagnosis rates remain low because men with PD may be too uncomfortable to speak up and get help.[5]

About XIAFLEX®
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.

- **Contraindications:** 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

- **Corporal Rupture or Other Serious Injury to the Penis:** 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. Cases of localized skin and soft tissue necrosis occurring as sequelae of penile hematoma, some requiring surgical intervention, have been reported post-marketing

- **Hypersensitivity Reactions, Including Anaphylaxis:** 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

- **Risk of Bleeding in Patients with Abnormal Coagulation:** 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)

- **Acute Post-Injection Back Pain Reactions:** Post approval reports of acute lower back pain reactions, sometimes accompanied by radiation to the lower extremities, chest and arms, muscle spasms, chest pain, paresthesias, headache, and dyspnea, have been received by patients treated with XIAFLEX for Peyronie's disease. These events can be mild to severe in intensity. The events typically lasted for 15 minutes and typically did not require intervention. Administer the smallest number of treatment cycles necessary to treat the patient's curvature deformity

Adverse Reactions
Clinical trials

- 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.

Post-marketing experience

- Acute post-injection lower back pain reactions have occurred in close temporal proximity to XIAFLEX treatments
- Cases of localized skin and soft tissue necrosis events as sequelae of penile hematoma, some of which required surgical intervention
- Syncope and presyncope have been reported in men treated with XIAFLEX for Peyronie's disease. Most, but not all cases occurred in the immediate treatment period or within 1-2 days following injection. Bodily injuries associated with the syncopal events have been reported

Click for full Prescribing Information, including Boxed Warning and Medication Guide.

About Endo
Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Dr. Mills, any statements relating to product efficacy, therapeutic outcomes or treatment responses, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; any actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the risks and uncertainties associated with chapter 11 proceedings; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the risk that the Company's chapter 11 cases may be converted to cases under chapter 7 of the Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results; the Company's ability to discharge claims in chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; the risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in chapter 11 proceedings; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; and the Company's ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

Additional information concerning risk factors, including those referenced above, can be found in press releases issued by the Company, as well as the Company's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

References:

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3. Stuntz M, Perlaky A, des Vignes F, et al. *PLoS One*. 2016;11(2):e0150157.
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