



Endo Presents New Data at the American Orthopaedic Foot & Ankle Society Annual Meeting

September 21, 2023

DUBLIN, Sept. 21, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that data from clinical studies of collagenase clostridium histolyticum (CCH) in patients with plantar fibromatosis will be presented during the American Orthopaedic Foot & Ankle Society's (AOFAS) annual scientific meeting. The meeting is taking place through September 23 in Louisville, Kentucky.



Three presentations cover data from the Phase 1 clinical study of CCH in patients with plantar fibromatosis. Results demonstrated improvement in nodule hardness and in patient and physician satisfaction scores. In addition, the CCH safety profile was consistent with the known CCH safety profile from other clinical studies and indications. Most adverse events were rated as mild to moderate, and there were no reported treatment-related serious adverse events.

A fourth presentation provides real-world treatment patterns derived from a retrospective observational study that compiles a large database of newly diagnosed patients with plantar fibromatosis. These new data address a gap in our knowledge of plantar fibromatosis treatments.

"We're pleased to share information and facilitate a better understanding of plantar fibromatosis in an effort to help improve treatment outcomes," said James P. Tursi, MD, Executive Vice President, Global Research & Development at Endo. "We look forward to presenting our clinical study data as we explore a potential nonsurgical option in patients with plantar fibromatosis."

CCH is not approved for use in treating patients with plantar fibromatosis. Endo has completed a Phase 2 study and anticipates that the pivotal Phase 3 program will begin later this year.

The four presentations are below:

- **NEW:** Treatment patterns for plantar fibromatosis in the United States: a retrospective observational study (e-poster presentation)
 - Authors: Jill Davis, MS; Aimee Near, MPH; David Hurley, MD; Laurence Djatche, PharmD, MS; Jenny Tse, MS; Riddhi P. Doshi, PhD, MBBS, MPH; Elizabeth J. Wang, MS; Luis A. Ortega, MD; David G. Armstrong, MD, PhD, MS
- Participant Satisfaction and Investigator Assessment of Collagenase Clostridium Histolyticum Injection as a Nonsurgical Intralesional Treatment Option for Plantar Fibromatosis (podium presentation)
 - Authors: Christopher J. Anderson, DPM; Richard A. Pollak, DPM; David Hernandez, MD; Shannon R. Dalton, PhD; Qinfang Xiang, PhD; Saji Vijayan, MBBS; Luis Ortega, MD; Joseph M. Caporusso, DPM
- Safety Data from a Study of Collagenase Clostridium Histolyticum Injection in Participants With Plantar Fibromatosis (poster presentation)
 - Authors: Richard A. Pollak, DPM; David Hernandez, MD; Christopher J. Anderson, DPM; Shannon R. Dalton, PhD; Qinfang Xiang, PhD; Saji Vijayan, MBBS; Luis Ortega, MD; Joseph M. Caporusso, DPM
- Collagenase Clostridium Histolyticum Injection in Patients With Plantar Fibromatosis: A Randomized, Open-Label, Dose-Ranging Study (e-podium presentation)
 - Authors: Christopher J. Anderson, DPM; Luis Ortega, MD; Joseph M. Caporusso, DPM; Richard A. Pollak, DPM; David Hernandez, MD; Shannon R. Dalton, PhD; Qinfang Xiang, PhD; Saji Vijayan, MBBS

About Plantar Fibromatosis

Plantar fibromatosis (PFI) or Ledderhose disease, sometimes termed "Dupuytren's disease of the foot," is a hyperproliferative fibrous tissue disorder resulting in the formation of nodules along the plantar fascia, the thick connective tissue that supports the arch of the foot, which is often painful. There

is no cure for PFI. Symptom management options include custom insoles, topical treatments, over-the-counter pain and anti-inflammatory medications, radiation therapy and steroid injections, and ultimately, surgery may be required to remove the nodules.

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. Tursi, any statements relating to product efficacy, clinical trials or studies, potential treatments or indications, therapeutic outcomes or treatment responses, safety or adverse events, 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," "intend," "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.

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