



Endo Presents Plantar Fibromatosis and Plantar Fasciitis Data at the American Podiatric Medical Association Annual Meeting

July 24, 2025

MALVERN, Pa., July 24, 2025 /PRNewswire/ -- Endo, Inc. (OTCQX: NDOI) announced today that three presentations related to plantar fibromatosis (PFI) and plantar fasciitis (PFA) will be shared during the American Podiatric Medical Association Annual Meeting, taking place July 24-27, 2025.



The first two presentations cover findings from Phase 1 and Phase 2 studies of collagenase clostridium histolyticum (CCH) in patients with PFA and PFI, respectively, while a third presentation features a retrospective analysis of insights from patients with PFI.

"We're pleased to share clinical trial data with healthcare providers as part of our ongoing efforts to help improve patient care and highlight our clinical development strategy," said James P. Tursi, M.D., Executive Vice President, Global Research & Development at Endo. "We are advancing a Phase 3 study aimed at exploring a potential nonsurgical treatment option for patients with PFI, further demonstrating our commitment to developing medicines that address challenging and burdensome conditions."

The three Endo-supported presentations are below:

- Collagenase Clostridium Histolyticum (CCH) in Patients With Plantar Fibromatosis (PFI): Post hoc Analysis of a Phase 2, Double-blind, Randomized, Placebo-Controlled Study
 - Authors: C. James Anderson, DPM; Ira Gottlieb DPM; Jason Levy, DPM, FACFAS; Saadiq El-Amin, MD, PhD; Sara E. Suttle, DPM, FACFAS; James Tursi, MD; Nigel Jones, PharmD; Luis Ortega, MD; Gongfu Zhou, PhD; Joseph Caporusso, DPM
- Understanding the Lived Experiences of People With Plantar Fibromatosis (PFI): A Mixed Methods Study
 - Authors: Joseph Caporusso, DPM; David Hurley, MD; Carrie Lewis, MS; Gary Manley, BSc; Laura Iliescu, MSc; and Luis Ortega, MD
- A Phase 1, Single-Blind, Randomized, Placebo-Controlled Dose Escalation Study to Assess Collagenase Clostridium Histolyticum (CCH) vs Placebo in Patients With Plantar Fasciitis (PFA)
 - Authors: Joseph Caporusso, DPM; Ira Gottlieb, DPM; Jason Levy, DPM; Saadiq El-Amin, MD, PhD; Sara Suttle, DPM; James Tursi, MD; Nigel Jones, PharmD; Luis Ortega, MD; Jeffrey Andrews, MS; C. James Anderson, DPM

CCH is not approved for use in treating patients with PFI or PFA. Endo is currently enrolling patients in the pivotal Phase 3 program for PFI.

About the Phase 2 PFI Study

A post hoc analysis of Phase 2 data identified a subgroup of PFI patients who appeared to respond well to CCH treatment. After excluding certain patients, those treated with CCH showed improvements in pain, nodule hardness, and overall condition compared to placebo. The subgroup also demonstrated greater treatment benefits than the original study population. A Phase 3 trial is currently underway with this refined population.

About the PFI Retrospective Analysis

The retrospective analysis of 91 patients synthesizes three patient voice studies, revealing that individuals with PFI are experiencing varying degrees of pain—those reporting moderate to severe pain face greater physical, emotional, and daily life burdens. Participants expressed dissatisfaction with current treatments and a strong interest in nonsurgical options like collagenase clostridium histolyticum, highlighting a need for therapies that reduce or halt nodule growth.

About the Phase 1 PFA Study

A Phase 1 proof-of-concept study evaluated the safety, tolerability, and effectiveness of a single CCH dose for PFA. The safety profile aligned with known adverse events (AE) and were mostly rated mild to moderate. Higher CCH doses had more frequent and severe AEs. CCH treatment showed improvements across all effectiveness measures compared to placebo, though

significance was not assessed. These results supported further investigation in a Phase 2 trial.

About Plantar Fibromatosis

PFI or Ledderhose disease is a hyperproliferative fibrous tissue disorder resulting in the formation of collagen 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 (orthotics), 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 Plantar Fasciitis

PFA causes foot discomfort due to inflammation and degeneration of the tissue connecting the heel to the toes, resulting in prominent heel pain. It is especially noticeable when starting to walk in the morning or after prolonged sitting or standing. There is no cure for PFA. Symptom management options include conservative options such as orthotics, icing, stretching, bracing, over the counter pain and anti-inflammatory medications with surgery reserved for more chronic presentations to relieve the tension in the plantar fascia.

About Endo

Endo is a diversified pharmaceutical company boldly transforming insights into life-enhancing therapies. Our passionate team members collaborate to develop and deliver these essential medicines. Together, we are committed to helping everyone we serve live their best life. Learn more at www.endo.com or connect with us on [LinkedIn](#).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements including, but not limited to, the statements by Dr. Tursi and any statements relating to product efficacy, potential treatments or indications, 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 such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intends," "guidance," "future," "potential" 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, some of which Endo may not currently be able to predict. Although Endo believes that these forward-looking statements and other information are based upon reasonable assumptions and expectations, readers should not place undue reliance on these or any other forward-looking statements and information. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the following: clinical trial results; changes in competitive, market or regulatory conditions; changes in legislation or regulations; the ability to obtain and maintain adequate protection for intellectual property rights; the impacts of competition; the timing and uncertainty of the results of the research and development and the regulatory processes; health care and cost containment reforms, including government pricing, tax and reimbursement policies; litigation and other disputes; consumer and physician acceptance of current and new products; the performance of third parties upon whom we rely for goods and services; issues associated with our supply chain; the ability to develop and expand our product pipeline, to launch new products and to continue to develop the market for our products; and the proposed business combination transaction between Endo and Mallinckrodt. 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. Additional information concerning risk factors, including those referenced above, can be found in press releases issued by Endo and in Endo's public filings with the U.S. Securities and Exchange Commission, including the discussion under the heading "Risk Factors" in Endo's most recent Form 10-K and Form 10-Q.

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