Endo Provides Top-Line Results from Phase 2 Study of Collagenase Clostridium Histolyticum (CCH) in Participants With Plantar Fibromatosis

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DUBLIN, March 13, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) today announced top-line results from its Phase 2 clinical study of collagenase clostridium histolyticum (CCH) in participants with plantar fibromatosis. While the primary endpoint when analyzed with the overall study population did not meet statistical significance, a large patient sub-population showed statistically significant improvement. The primary endpoint was improvement from baseline in the Foot Function Index (FFI) Pain Scale score when compared to those receiving placebo.

The overall clinical study population met some key secondary and exploratory endpoints, including the investigator assessment of improvement (Clinician Global Impression of Change), nodule hardness and improvement in nodule consistency. The large patient sub-population met the primary endpoint, as well as the majority of all secondary and exploratory endpoints.

The CCH safety profile in the Phase 2 clinical study was consistent with the known CCH safety profile from other studies. Most adverse events were rated as mild to moderate and there were no treatment-related serious adverse events.

"We believe we have a clear path forward to Phase 3 development for CCH in patients with plantar fibromatosis," said James P. Tursi, M.D., Executive Vice President, Global Research & Development at Endo. "The Phase 2 clinical study data will help us refine our Phase 3 clinical study design, and we plan to begin the pivotal program later this year. We remain committed to developing and providing nonsurgical treatments to help everyone we serve live their best lives."

"This clinical study was designed to test multiple variables with a goal to identify an optimal path to Phase 3 development, and we were successful in doing that," said Dr. Joseph M. Caporusso, a Texas-based podiatrist and a lead clinical investigator for the Phase 2 study. "We look forward to further investigation of CCH in patients with plantar fibromatosis with the ultimate goal of providing patients the first non-surgical treatment for this condition."

About Phase II Clinical Trial
The double-blind, placebo-controlled Phase 2 clinical trial enrolled 176 total participants with single or multiple nodules. Participants were randomized 1:1 to receive CCH or placebo. Participants received up to two treatments, depending on nodule size, separated by a minimum of 28 days. At pre-specified timepoints, participants completed the Foot Function Index (FFI), a patient-completed questionnaire that measures the impact of certain foot disorders in terms of pain, disability and activity restriction.

The primary endpoint was the change from baseline in the FFI Pain Scale score at the day 57 visit. Additional endpoints included changes in the FFI Disability Scale score, FFI Activity Restriction Scale score and numerical pain score, as well as changes in nodule hardness and consistency.

About Plantar Fibromatosis
Plantar fibromatosis (PFI), 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.

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 Drs. Tursi and Caporusso and

any statements relating to clinical trials or studies, potential treatments or indications, future research, safety, adverse events, development plans, timelines or expectations, 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. Copies of the Company's press releases and additional information about the Company are available at www.endo.com or you can contact the Company's Investor Relations Department at relations.investor@endo.com.

View original content to download multimedia:https://www.prnewswire.com/news-releases/endo-provides-top-line-results-from-phase-2-study-of-collagenase-clostridium-histolyticum-cch-in-participants-with-plantar-fibromatosis-301770644.html

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