Endo Presents New Investigational Collagenase Clostridium Histolyticum Data at the American Podiatric Medical Association Annual Scientific Meeting

July 29, 2021

DUBLIN, July 29, 2021 /PRNewswire/ --

- *Encouraging Phase I safety and tolerability results of CCH as a nonsurgical treatment of plantar fibromatosis*
- *Research to continue to Phase II; retreatment phase also is ongoing in eligible patients*

Endo International plc (NASDAQ:ENDP) announced today initial results from a Phase I study (EN3835–105) evaluating collagenase clostridium histolyticum (CCH) for the treatment of plantar fibromatosis. The data are being presented as an e-poster at the American Podiatric Medical Association Annual Scientific Meeting, The National, in Denver, July 29–August 1. The poster is viewable here through August 1.

Plantar fibromatosis (sometimes referred to as Ledderhose disease) is a rare condition in which an uncontrolled proliferation of fibrous tissue causes the formation of nodules on the bottom of the foot along the plantar fascia. If left untreated, the nodules can cause pain, discomfort, swelling and difficulty walking.[1]

"The current treatment of plantar fibromatosis is primarily focused on relieving pain and swelling, as options to effectively treat this condition and remove the nodules are limited to more invasive surgical procedures[1]," said Richard Pollak, DPM, MS, the lead study author and president of Endeavor Clinical Trials and San Antonio Podiatry Associates in Texas. "These early-phase data provide new evidence suggesting that CCH could potentially be a nonsurgical option to treat this condition."

CCH is composed of two purified collagenases that work to break down collagen when injected into fibrous tissue.[2] The Phase I, open-label, randomized, dose-ranging study (EN3835–105) presented at APMA is the first trial to explore CCH for the treatment of plantar fibromatosis.

"These Phase I data represent Endo's potential introduction into the podiatric space, as well as our commitment to orthopedics, and our continuing efforts to advance CCH as a nonsurgical treatment option for additional target conditions," said Matthew Davis, M.D., R.Ph., Endo's Chief Scientific Officer. "We are encouraged by these initial findings and are excited to progress our clinical research program to a Phase II study in plantar fibromatosis."

About EN3835-105

EN3835–105 was an open-label, randomized, dose-ranging study that enrolled 24 patients ages 18 years or older with plantar fibromatosis. Participants with a palpable/ultrasound-measurable nodule in one or both feet were randomly assigned to one of the three dosing groups administered on Day 1: CCH 0.6 mg/mL, 1.2 mg/mL, or 2.25 mg/mL (0.12, 0.24, or 0.45 mg per injection, respectively). Nodules measuring ≤1.5 cm in diameter (by ultrasound) were treated with one intralesional injection and nodules >1.5 cm in diameter were treated with two injections. In total, 31 nodules were treated across all three dosing groups.

For the primary outcome, treatment was generally well tolerated across all dosing groups, with no discontinuations due to treatment-related adverse events (AEs) and no serious treatment-related AEs reported. All treatment-related AEs were mild or moderate in intensity, with the most common being injection-site bruising, pain and swelling. Most (70.9%) of these AEs resolved within 21 days.

For the secondary endpoints, more than 72% of patients across the three treatment groups indicated being "very satisfied" or "quite satisfied" with the first treatment of their nodule(s) at day 57. In addition, most investigators (>72%) reported improvements in the nodules across the treatment groups.

The study also assessed foot function using a modified version of the Foot Function Index-Short Form-23 (FFI-SF-23),[3] which measures foot pain, disability and difficulty performing activities. Nodule characteristics also were assessed by investigators using palpation to determine consistency (e.g., hard, firm, soft). At day 57, all treatment groups demonstrated improvements in modified FFI-SF-23 composite score and nodule consistency.

Participants who received CCH 2.25 mg/mL had the highest percentage improvement from baseline in FFI-SF-23 composite score (78.8% compared with 41%, 0.6 mg/mL and 44.8%, 1.2 mg/mL). Improvement in softening of nodule consistency (≥1 level) from baseline also were higher in the CCH 2.25 mg/mL group as well as the 1.2 mg/mL group (90% each, compared with 72.2%, 0.6 mg/mL).

About CCH

Collagenase clostridium histolyticum (CCH) is composed of 2 purified collagenases (AUX-I and AUX-II) that hydrolyze collagen under physiologic conditions, resulting in disruption of collagen containing structures.

CCH (XIAFLEX®) is currently approved by FDA for the treatment of adults with Dupuytren's contracture with a palpable cord and the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of ≥30 degrees at the start of therapy.[2]

About Endo International plc

Endo (NASDAQ: ENDP) 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 a global team of passionate employees collaborating to bring the best 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 Statement

This press release contains certain 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. Davis and Pollak, and other statements regarding the potential progress, timing and results of clinical studies and trials, research and development outcomes, product safety, efficacy, effectiveness, 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.

References

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