



## Endo Announces Publication of New XIAFLEX® (collagenase clostridium histolyticum) Survey Data in Journal of Hand Surgery Global Open

January 24, 2024

DUBLIN, Jan. 24, 2024 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that the peer-reviewed *Journal of Hand Surgery Global Open* published [Collagenase Clostridium Histolyticum for the Treatment of Dupuytren Disease: A Delphi-Based Consensus Study](#).<sup>1</sup>



Consensus-based study findings among expert hand surgeons indicate that XIAFLEX® (collagenase clostridium histolyticum) has a wide-ranging application for the appropriate treatment of Dupuytren's contracture in patients with varying degrees of disease severity and functional impairment. Results from the published research indicate a high level of consensus for using XIAFLEX for the treatment of one- or two-finger metacarpophalangeal (MP) joint contractures, most one- or two-finger proximal interphalangeal (PIP) joint contractures, and most combined MP and PIP joint contractures.

"Healthcare providers and patients can choose among multiple surgical and nonsurgical treatment options for Dupuytren's disease, and without established guidelines, the process for sorting through those choices can be overwhelming," said Dr. Gary M. Pess, a hand and upper extremity surgeon and lead author of the study. "This study provides insight from experienced hand surgeons about using XIAFLEX to treat varying degrees of Dupuytren's contracture."

Dupuytren's disease is a heterogenous fibroproliferative condition of the palmar fascia characterized by the development of fascial nodules and cords that may result in digital contracture affecting hand function.<sup>2,3</sup> XIAFLEX is a nonsurgical treatment option for Dupuytren's contracture when a "cord" can be felt composed of two purified collagenases that work to break down collagen when injected into fibrous tissue.<sup>4</sup>

### About the Report

Researchers used a modified Delphi method employing three successive, blinded online survey rounds to capture the clinical expertise of panelists and determine if consensus could be reached regarding the use of XIAFLEX for the treatment of Dupuytren's contracture.<sup>1</sup>

In Round 1, 22 real-world case scenarios were used to determine the panelists' recommendations for using XIAFLEX to treat metacarpophalangeal (MP) and/or proximal interphalangeal (PIP) joint contractures involving a single finger or 2 fingers, with varying degrees of contracture and clinical severity. Each scenario presented a distinct contracture(s) with a series of statements to evaluate the impact of patient- or disease-related features (e.g., age, recurrence, risk of anesthesia, Dupuytren diathesis, poor-quality skin, and post-fasciectomy scarring) on the clinical decision to use XIAFLEX.

Researchers captured responses using either yes/no responses or a 5-point Likert scale ("strongly agree," "agree," "deficient information," "disagree," and "strongly disagree"). Level of agreement for each statement was determined, with a consensus threshold of  $\geq 66.7\%$  for agreement ("strongly agree" and "agree") or disagreement ("strongly disagree" and "disagree").

Round 2 included statements that did not meet the  $\geq 66.7\%$  threshold for consensus in round 1 and scenarios that explored the "impact of patient decision" (e.g., patient declines open surgical procedure). Statements were rated as described for round 1.

Round 3 reassessed the statements that did not reach consensus in round 2 and explored the clinical decision-making process using an open-ended response methodology.

Of the 33 hand surgeons who were invited based on their expertise and experience with treatment for Dupuytren's contracture, 22 agreed to participate in the survey; 20 completed round 1 of the survey, and 19 completed rounds 2 and 3. Overall, 80% had practiced medicine for at least 15 years, and all had completed a fellowship in hand surgery. Ninety percent were board-certified hand surgeons.

Consensus-based study findings among expert hand surgeons point to wide-ranging application of XIAFLEX for the treatment of Dupuytren's contracture for patients with varying degrees of disease severity and functional impairment.

## WHAT IS XIAFLEX®?

XIAFLEX is a prescription medicine used to treat adults with Dupuytren's contracture when a "cord" can be felt. It is not known if XIAFLEX is safe and effective in children under the age of 18.

## IMPORTANT SAFETY INFORMATION FOR XIAFLEX

**Do not receive XIAFLEX if you** have had an allergic reaction to collagenase clostridium histolyticum or any of the ingredients in XIAFLEX, or to any other collagenase product. See the end of the Medication Guide for a complete list of ingredients in XIAFLEX.

**XIAFLEX can cause serious side effects, including:**

- **Tendon rupture or ligament damage.** Receiving an injection of XIAFLEX may cause damage to a tendon or ligament in your hand and cause it to break or weaken. This could require surgery to fix the damaged tendon or ligament. Call your healthcare provider right away if you have trouble bending your injected finger (towards the wrist) after the swelling goes down or you have problems using your treated hand after your follow-up visit
- **Nerve injury or other serious injury of the hand.** After finger procedures, some people developed tears in the skin (lacerations), and local skin and soft-tissue necrosis (death of skin cells). Some lacerations and necrosis required skin grafting, or other surgery including amputation. **Call your healthcare provider right away** if you get numbness, tingling, increased pain, or tears in the skin (laceration) in your treated finger or hand after your injection or after your follow-up visit
- **Hypersensitivity reactions, including anaphylaxis.** Severe allergic reactions can happen in people who receive XIAFLEX because it contains foreign proteins. **Call your healthcare provider right away if you have any of these symptoms of an allergic reaction after an injection of XIAFLEX:**
  - hives
  - swollen face
  - breathing trouble
  - chest pain
  - low blood pressure
  - dizziness or fainting
- **Fainting.** Fainting (passing out) or near fainting can happen in people who receive XIAFLEX, especially following finger procedures  
**If you have dizziness or feel faint after receiving XIAFLEX, lie down until the symptoms go away.**
- **Increased chance of bleeding.** Bleeding or bruising at the injection site can happen in people who receive XIAFLEX. Talk to your healthcare provider if you have a problem with your blood clotting. XIAFLEX may not be right for you.

**Before receiving XIAFLEX, tell your healthcare provider if you** have had an allergic reaction to a previous XIAFLEX injection, or have a bleeding problem or any other medical conditions. Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Using XIAFLEX with certain other medicines can cause serious side effects. Especially tell your healthcare provider if you take medicines to thin your blood (anticoagulants). If you are told to stop taking a blood thinner before your XIAFLEX injection, your healthcare provider should tell you when to restart the blood thinner. Ask your healthcare provider or pharmacist for a list of these medicines if you are unsure.

The most common side effects with XIAFLEX for the treatment of Dupuytren's contracture include:

- swelling of the injection site or the hand
- bruising or bleeding at the injection site
- pain or tenderness of the injection site or the hand
- swelling of the lymph nodes (glands) in the elbow or armpit
- itching
- breaks in the skin
- redness or warmth of the skin
- pain in the armpit

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects with XIAFLEX. For more information, ask your healthcare provider or pharmacist.

Click for full [Prescribing Information](#), including [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](http://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. Pess, 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 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 complete a chapter 11 plan of reorganization or to pursue an alternative emergence transaction; 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

1. Pess G, et al. *J Hand Surg Online*. 2023; 1-8.
2. Warwick D, et al. *Int. J Clin Rheumatol*. 2012;7(3):309-323.
3. Warwick D. *J Hand Surg Eur* Vol. 2017;42(7):665-672.
4. XIAFLEX® (collagenase clostridium histolyticum) for injection, for intralesional use [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.

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