Keenova Publishes XIAFLEX® (collagenase clostridium histolyticum) Analysis in Journal of Hand Surgery Global Online

March 3, 2026

Manuscript appears in a peer-reviewed journal for the first time

- *The Phase 4 retrospective study evaluates previously generated XIAFLEX® (*collagenase clostridium histolyticum*) data for recurrent Dupuytren contracture after surgery.*
- *Findings suggest XIAFLEX may offer an alternative to repeat surgery and add to existing insights on recurrence management.*
- *Keenova uses research to help strengthen clinical resources to support providers and patient care.*

DUBLIN, March 3, 2026 /PRNewswire/ -- Keenova Therapeutics plc announced the first-time publication of a retrospective analysis using previously generated XIAFLEX® (collagenase clostridium histolyticum) data. The analysis evaluates treatment of Dupuytren contracture (DC) recurrence after surgical correction. The manuscript appears in the peer-reviewed *Journal of Hand Surgery Global Online,* available here.

Why It Matters

DC can return after any treatment, leaving patients and providers unsure about next steps. Keenova supports research that expands the evidence base and helps hand specialists understand how nonsurgical XIAFLEX may fit into recurrence management. This work advances Keenova's commitment to advancing disease awareness and improving support for both providers and patients.

The News

- The analysis evaluated XIAFLEX in patients who experienced recurrence at least six months after a previously successful surgery.
- Adverse events were consistent with prior reports of collagenase clostridium histolyticum (CCH) in patients without prior surgical treatment.
- The Phase 4 multicenter, noninterventional retrospective review analyzed medical records from 10 U.S. clinical centers.
- The review included patients who experienced recurrence at least six months after a successful surgical correction and received collagenase treatment between January 2010 and August 2020.
- Primary endpoints measured changes in joint contracture within 12 months of treatment.
- Secondary endpoints assessed "clinical success," defined as the percentage of joints with reduction in contracture to 0° to 5°, and adverse events.

Expert Perspective

"These findings may help healthcare providers better manage Dupuytren contracture recurrence in patients despite an initially successful surgery," said Clayton A. Peimer, MD, Adjunct Clinical Professor of Orthopedics at the Warren Alpert Medical School of Brown University and lead author. "In these situations, collagenase offers an effective nonsurgical alternative to repeat operative treatment. Our study adds important insight into the available options for recurrent Dupuytren contracture and supports improved choices and outcomes for patients."

Manuscript Details

- **Title:** Treatment of Dupuytren Contracture Recurrence After Surgery with Collagenase Clostridium Histolyticum: A Retrospective Multicenter Series
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About Dupuytren Contracture
Dupuytren contracture is a lifelong condition that may get worse over time. It's caused by a buildup of collagen in the hand, which

forms a rope-like cord that pulls fingers toward the palm so they can't be straightened. As Dupuytren's contracture progresses, it may become difficult for individuals to use their hand(s) for daily tasks and activities.[1,2] Dupuytren contracture affects an estimated 13 million Americans.[3,4*]

INDICATION

XIAFLEX is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.

IMPORTANT SAFETY INFORMATION

- XIAFLEX is contraindicated in patients with a history of hypersensitivity to XIAFLEX or to collagenase used in any other therapeutic application or application method

- In the controlled and uncontrolled portions of clinical trials in Dupuytren's contracture, flexor tendon ruptures occurred after XIAFLEX injection. Injection of XIAFLEX into collagen-containing structures such as tendons or ligaments of the hand may result in damage to those structures and possible permanent injury such as tendon rupture or ligament damage. Therefore, XIAFLEX should be injected only into the collagen cord with a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint contracture, and care should be taken to avoid injecting into tendons, nerves, blood vessels, or other collagen-containing structures of the hand. When injecting a cord affecting a PIP joint of the fifth finger, the needle insertion should not be more than 2 to 3 mm in depth and avoid injecting more than 4 mm distal to the palmar digital crease

- Other XIAFLEX-associated serious local adverse reactions in the controlled and uncontrolled portions of the clinical studies included pulley rupture, ligament injury, complex regional pain syndrome (CRPS), sensory abnormality of the hand, and skin laceration (tear). In a historically controlled post-marketing trial, the incidence of skin laceration (22%) was higher for subjects treated with two concurrent injections of XIAFLEX compared with subjects treated with up to three single injections in the placebo-controlled premarketing trials (9%). Post-marketing cases of skin laceration requiring skin graft after finger extension procedures and local skin and soft-tissue necrosis, some requiring skin grafting, or other surgical interventions including finger amputation have been reported. Signs or symptoms that may reflect serious injury to the injected finger/hand should be promptly evaluated because surgical intervention may be required

- Cases of syncope and presyncope have been reported in the post-marketing period in patients treated with XIAFLEX. In most cases in patients with Dupuytren's contracture, the injection procedure, finger extension procedure, or pain following the procedures were reported as potential triggers for the events, suggesting a vasovagal mechanism. Most, but not all, cases occurred in the immediate treatment period (injection or finger extension procedure) or within 1 to 2 days following the injection or finger extension procedure. If presyncopal symptoms occur, patients should remain recumbent until symptoms resolve. Syncope may be associated with bodily injuries, including concussion, head abrasion, and other accidental injuries

- In the controlled portions of the clinical trials in Dupuytren's contracture, a greater proportion of XIAFLEX-treated patients (15%) compared to placebo-treated patients (1%) had mild allergic reactions (pruritus) after up to 3 injections. The incidence of XIAFLEX-associated pruritus increased after more XIAFLEX injections in patients with Dupuytren's contracture

- Because XIAFLEX contains foreign proteins, severe allergic reactions to XIAFLEX can occur. Anaphylaxis was reported in a post-marketing clinical trial in one patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections

- In the XIAFLEX trials in Dupuytren's contracture, 70% and 38% of XIAFLEX-treated patients developed an ecchymosis/contusion or an injection site hemorrhage, respectively. Patients with abnormal coagulation (except for patients taking low-dose aspirin, eg, up to 150 mg per day) were excluded from participating in these studies. Therefore, the efficacy and safety of XIAFLEX in patients receiving anticoagulant medications (other than low-dose aspirin, eg, up to 150 mg per day) within 7 days prior to XIAFLEX administration is not known. In addition, it is recommended to avoid use of XIAFLEX in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin)

- In the XIAFLEX clinical trials for Dupuytren's contracture, the most common adverse reactions reported in ≥25% of patients treated with XIAFLEX and at an incidence greater than placebo were edema peripheral (eg, swelling of the injected hand), contusion, injection site hemorrhage, injection site reaction, and pain in the injected extremity.

- Post-marketing experience – Syncope and presyncope have been reported in patients treated with XIAFLEX. Most, but not all, cases occurred in the immediate treatment period or within 1 to 2 days following injection. Bodily injuries associated with the syncopal events have been reported

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About Keenova
Keenova Therapeutics is a leading global developer and manufacturer of branded therapeutics that strives to help patients with rare or unaddressed conditions live happier and healthier lives.

The Company's diversified brands portfolio is focused across a wide range of therapeutic areas of significant unmet need, including endocrinology, gastroenterology, hepatology, immunology, neonatal respiratory critical care, nephrology, neurology, pulmonology, ophthalmology, orthopedics, rheumatology and urology. Globally headquartered in Dublin, Ireland, Keenova benefits from a strong U.S. manufacturing footprint with facilities in Louisiana, New Jersey, New York, Pennsylvania and Wisconsin. To learn more, please visit www.keenova.com.

Keenova uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the Company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission ("SEC") disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

Information Regarding Forward-Looking Statements

There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: the expected benefits and synergies of the business combination with Endo ("Business Combination") may not be fully realized in a timely manner, or at all; the Company's increased indebtedness as a result of the Business Combination and significant transaction costs related to the Business Combination; the expected growth opportunities, profit improvements, cost savings and other benefits as a result of the spin-off of Par Health may not be fully realized in a timely manner, or at all; unanticipated costs, litigation and/or regulatory inquiries and investigations as a result of the spin-off of Par Health; risks associated with being a smaller, less diversified company as a result of the spin-off of Par Health; potential changes in the Company's business strategy and performance; exposure to global economic conditions and market uncertainty; governmental investigations and inquiries, regulatory actions, and lawsuits, in each case related to the Company's or its officers; the Company's contractual and court-ordered compliance obligations that, if violated, could result in penalties; compliance with and restrictions under the global settlement to resolve all opioid-related claims; matters related to Acthar Gel, including the settlement with governmental parties to resolve certain disputes and compliance with and restrictions under the related corporate integrity agreement; the ability to maintain relationships with the Company's suppliers, customers, employees and other third parties; scrutiny from governments, legislative bodies and enforcement agencies related to sales, marketing and pricing practices; pricing pressure on certain of the Company's products due to legal changes or changes in insurers' or other payers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs; the reimbursement practices of governmental health administration authorities, private health coverage insurers and other third-party payers; complex reporting and payment obligations under the Medicare and Medicaid rebate programs and other governmental purchasing and rebate programs; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations; changes in or failure to comply with relevant laws and regulations; any undesirable side effects caused by the Company's approved and investigational products, which could limit their commercial profile or result in other negative consequences; the Company's and its partners' ability to successfully develop, commercialize or launch new products or expand commercial opportunities of existing products, including Acthar Gel (repository corticotropin injection) SelfJect, the INOmax Evolve DS delivery system, and XIAFLEX; the Company's ability to successfully identify or discover additional products or product candidates; the Company's ability to navigate price fluctuations and pressures, including the ability to achieve anticipated benefits of price increases of its products; competition; the Company's and its partners' ability to protect intellectual property rights, including in relation to ongoing and future litigation; limited clinical trial data for Acthar Gel; the timing, expense and uncertainty associated with clinical studies and related regulatory processes; product liability losses and other litigation liability; material health, safety and environmental laws and related liabilities; business development activities or other strategic transactions; attraction and retention of key personnel; the effectiveness of information technology infrastructure, including risks of external attacks or failures; customer concentration; the Company's reliance on certain individual products that are material to its financial performance; the Company's ability to receive sufficient procurement and production quotas granted by the U.S. Drug Enforcement Administration; complex manufacturing processes; reliance on third-party manufacturers and supply chain providers and related market disruptions; conducting business internationally; the Company's significant levels of intangible assets and related impairment testing; natural disasters or other catastrophic events; the Company's substantial indebtedness and settlement obligation, its ability to generate sufficient cash to reduce its indebtedness and its potential need and ability to incur further indebtedness; restrictions contained in the agreements governing the Company's indebtedness and settlement obligation on the Company's operations, future financings and use of proceeds; the Company's variable rate indebtedness; the Company's tax treatment by the Internal Revenue Service under Section 7874 and Section 382 of the Internal Revenue Code of 1986, as amended; future changes to applicable tax laws or the impact of disputes with governmental tax authorities; the impact of Irish laws; the comparability of the Company's post-emergence financial results and the projections filed with the U.S. Bankruptcy Court for the District of Delaware and the lack of comparability of the Company's historical financial statements and information contained in its financial statements after the adoption of fresh-start accounting following emergence from Mallinckrodt's and Endo's respective bankruptcy proceedings.

The "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the fiscal year ended December 27, 2024, its Quarterly Report on Form 10-Q for the quarterly period ended March 28, 2025, its Quarterly Report for the quarterly period ended June 27, 2025, its Quarterly Report for the quarterly period ended September 26, 2025, its Registration Statement on Form S-4, as amended, filed with the SEC, and other filings with the SEC, all of which are on file with the SEC and available from the SEC's website (www.sec.gov) and the Company's website (www.keenova.com), identify and describe in more detail the risks and uncertainties to which the Company's businesses are subject. There may be other risks and uncertainties that we are unable to predict at this time or that we currently

do not expect to have a material adverse effect on our business. The forward-looking statements made herein speak only as of the date hereof and the Company does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law. Given these uncertainties, one should not put undue reliance on any forward-looking statements.

* Dupuytren Contracture prevalence estimation calculation in the U.S.: Average Dupuytren contracture prevalence in the U.S. (5%) multiplied by U.S. adult population (~258 million adults per 2020 U.S. Census data) = ~13 million.

References

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3. "How common is Dupuytren disease?" *Dupuytren Research Group*. April 1, 2017. Accessed February 2, 2026. https://dupuytrens.org/faq
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