



Keenova Marks 100K Peyronie's Disease Patients--a Major Milestone for an Often-Stigmatized Men's Health Condition

January 21, 2026

- 100,000 men have been prescribed XIAFLEX® (collagenase clostridium histolyticum) to treat their Peyronie's disease^{1*}
- Diagnosis rates for the condition remain low because men with PD may be too uncomfortable to speak up and get help
- In 2026, Keenova will focus on building awareness to help improve diagnosis rates with new and enhanced initiatives, including evolved marketing campaigns and more patient voices

DUBLIN, Jan. 21, 2026 /PRNewswire/ -- Keenova Therapeutics plc announced today that it reached a milestone: **100,000 patients with Peyronie's disease (PD) have been prescribed XIAFLEX® (collagenase clostridium histolyticum).**^{1*}



XIAFLEX is the **only FDA-approved nonsurgical treatment for adult men with PD** who have a "plaque" that can be felt and a curve in their penis greater than 30 degrees when treatment is started.² 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.

Why It Matters

XIAFLEX launched in 2013 as the first and only FDA-approved nonsurgical treatment for PD. The condition is thought to be more prevalent than reported.² Diagnosis rates remain low because men with PD may be too uncomfortable to speak up and get help.³

"This milestone is a testament to the strength of those patients who have overcome their physical and emotional discomfort to seek help for PD," said Dan Plunkett, Executive Director of Marketing at Keenova.

"The achievement also reflects the dedication and collaboration of teams across the patient journey—from researchers who developed the treatment to the urology specialists who care for patients and administer XIAFLEX," Plunkett continued. "At Keenova, we are proud of our continued commitment to men's health and to supporting men with Peyronie's disease."

Building Awareness and Impact in 2026

Keenova will continue its awareness efforts in 2026 and empower men to speak with a urology specialist and explore whether XIAFLEX is right for them.

- **Marketing campaigns to reach men and partners:** Keenova's campaigns—including Bent Carrot and [Prime Time](#)—are running on digital and social channels and on streaming and video platforms such as Prime Video, CBS, HBO Max, Hulu, and Peacock. This year, Keenova will evolve its messaging to engage the partners of those with PD to help spark conversations about the condition.
- **Patient voices on social media:** Social media sites like Meta and Reddit have proven to be powerful drivers for educating adult men with PD and empowering them to act. Keenova will expand its efforts on social media and amplify patient experiences and stories on those platforms.
- **Mixed reality tool for providers to enhance technique:** Launched in 2025, the Spatial Computing Injection Simulator allows urology specialists to interact simultaneously with both physical and digital objects—blending a physical penile model and digital content via an Apple Vision Pro app—to help refine their injection technique. Keenova will expand use and access to the simulator to help healthcare providers build clinical confidence.

About Peyronie's Disease

Peyronie's disease is a condition in which a buildup of fibrous scar tissue causes a curvature deformity of the penis. This curvature can be bothersome during arousal and intimacy.⁴ Diagnosis rates remain low because men with PD may be too uncomfortable to speak up and get help.³

* As of January 2026, 100,020 men have been prescribed XIAFLEX for PD. Calculations and estimations based on transactions for XIAFLEX for PD from January 1, 2014 to January 13, 2026.¹

IMPORTANT SAFETY INFORMATION

Do not receive XIAFLEX if:

- the Peyronie's plaque to be treated involves the "tube" that your urine passes through (urethra).
- you are allergic 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:

1. Penile fracture (corporal rupture) or other serious injury to the penis. Receiving an injection of XIAFLEX may cause damage to the tubes in your penis called the corpora. After treatment with XIAFLEX, one of these tubes may break during an erection. This is called a corporal rupture or penile fracture. This could require surgery to fix the damaged area. Damage to your penis might not get better after a corporal rupture.

- After treatment with XIAFLEX, blood vessels in your penis may also break, causing blood to collect under the skin (hematoma). This could require a procedure to drain the blood from under the skin. If a hematoma appears, skin and soft tissue necrosis (death of skin cells) may develop in that area, which could require surgery.

Symptoms of corporal rupture or other serious injury to your penis may include:

- a popping sound or sensation in an erect penis
- sudden loss of the ability to maintain an erection
- pain in your penis
- purple bruising and swelling of your penis
- difficulty urinating or blood in the urine

Call your healthcare provider right away if you have any of the symptoms of corporal rupture or serious injury to the penis listed above.

Do not have sex or any other sexual activity between the first and second injections of a treatment cycle.

Do not have sex or have any other sexual activity for at least 4 weeks after the second injection of a treatment cycle with XIAFLEX and after any pain and swelling has gone away.

XIAFLEX for the treatment of Peyronie's disease is only available through a restricted program called the XIAFLEX Risk Evaluation and Mitigation Strategy (REMS) Program.

2. 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

3. Back pain reactions. After receiving an injection of XIAFLEX for Peyronie's disease, you may suddenly feel back pain, including severe lower back pain moving to your legs, feet, chest and arms. The back pain may also include spasms and make it hard to walk. These symptoms usually go away in 15 minutes or less, but may last longer.

Tell your healthcare provider right away if you have sudden back pain, chest pain, or hard time walking after an injection.

4. Fainting. Fainting (passing out) or near fainting can happen in men who receive XIAFLEX, especially if they have severe penile pain.

If you have dizziness or feel faint after receiving XIAFLEX, lie down until the symptoms go away.

Before receiving XIAFLEX, tell your healthcare provider if you have had an allergic reaction to a previous XIAFLEX injection, have a bleeding problem, received XIAFLEX for another condition, or any other medical conditions. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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 not sure.

What should I avoid while receiving XIAFLEX?

Avoid situations that may cause you to strain your stomach (abdominal) muscles, such as straining during bowel movements.

Do not use a vacuum erection device during your treatment with XIAFLEX.

XIAFLEX can cause serious side effects, including 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.

The most common side effects with XIAFLEX for the treatment of Peyronie's disease include:

- a small collection of blood under the skin at the injection site (hematoma)
- swelling at the injection site or along your penis
- pain or tenderness at the injection site, along your penis and above your penis
- penis bruising
- itching of your penis or scrotum (genitals)
- painful erection
- erection problems (erectile dysfunction)
- changes in the color of the skin of your penis
- blisters at the injection site
- pain with sex
- a lump at the injection site (nodule)

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. You may report side effects to FDA at 1-800-FDA-1088.

WHAT IS XIAFLEX®?

XIAFLEX is a prescription medicine used to treat adult men with Peyronie's disease who have a "plaque" that can be felt and a curve in their penis greater than 30 degrees when treatment is started.

It is not known if XIAFLEX is safe and effective in children under the age of 18.

Rx Only

Click for full [Prescribing Information](#), including **BOXED WARNING** and [Medication Guide](#).

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.

References:


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4. Hellstrom WJ. *Int J Impot Res*. 2003;15:S91-S92.

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