Keenova Announces Newly Updated Peyronie's Disease Study Results at American Urology Association Meeting

May 15, 2026

DUBLIN, May 15, 2026 /PRNewswire/ -- Keenova Therapeutics plc announced today that new and final updated data from its dedicated ventral curvature analysis of Peyronie's disease and XIAFLEX® (collagenase clostridium histolyticum) will be shared at the American Urological Association (AUA) annual meeting, taking place May 15–18, 2026. The data to be presented will highlight that the clinical effectiveness and safety of XIAFLEX (collagenase clostridium histolyticum) in patients with ventral curvature are consistent with outcomes observed in patients with other clinical presentations of Peyronie's disease.

"These new results are consistent with earlier studies and reinforce that XIAFLEX (collagenase clostridium histolyticum) is both effective and well tolerated for men with Peyronie's disease, including those with ventral curvature," said Jesse Mills, MD, Clinical Professor and Director of the Men's Clinic at UCLA, who is presenting the findings. "Such outcomes are encouraging to clinicians and patients looking for nonsurgical treatment options, and they underscore the importance of continued research to further expand our understanding of Peyronie's disease and its treatment."

Presentation Details

- **Title:** Final Results of a Multicenter, Retrospective Analysis of Collagenase Clostridium Histolyticum (CCH) for Ventral Penile Curvature in Peyronie's Disease
- **Authors:** Matthew J. Ziegelmann, MD; Billy H. Cordon, MD; Majdee M. Islam, MD; Alexander J. Tatem, MD; Richard C. Bennett, MD; Faysal A. Yafi, MD, FRCSC; Peter Bajic, MD; Nelson E. Bennett, Jr., MD; Helen L. Bernie, DO, MPH; Marcelo Mass-Lindenbaum, MD; Muhammed A. M. Hammad, MBBCh, MS; Kristen Gumpf, PA-C; David Hurley, MD; Jeffrey Andrews, MS; Tina Rezakhani, PharmD, MBA; Marian Ayad, PharmD, BCPS; Mohit Khera, MD, MBA, MPH; Bruce R. Kava, MD; Jesse N. Mills, MD

About Peyronie's Disease
Peyronie's disease (PD) 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.[1] It is estimated that PD can affect as many as 1 in 10 men in the U.S.,[2*] but diagnosis rates remain low because men with PD may be too uncomfortable to speak up and get help.[3]

XIAFLEX® PD Professional Indication and Important Safety Information

INDICATION
XIAFLEX® is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

IMPORTANT SAFETY INFORMATION FOR XIAFLEX

WARNING: CORPORAL RUPTURE (PENILE FRACTURE) OR OTHER SERIOUS PENILE INJURY IN THE TREATMENT OF PEYRONIE'S DISEASE

Corporal rupture (penile fracture) was reported as an adverse reaction in 5 of 1044 (0.5%) XIAFLEX-treated patients in clinical studies. In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 (3.7%) XIAFLEX-treated patients.

Signs or symptoms that may reflect serious penile injury should be promptly evaluated to assess for corporal rupture or severe penile hematoma which may require surgical intervention.

Because of the risks of corporal rupture or other serious penile injury, XIAFLEX is available for the treatment of Peyronie's disease only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX REMS Program.

- **Contraindications:** XIAFLEX is contraindicated in the treatment of Peyronie's plaques that involve the penile urethra due

to potential risk to this structure and in patients with a history of hypersensitivity to XIAFLEX or to collagenase used in any other therapeutic application or application method

- **Corporal Rupture or Other Serious Injury to the Penis:** Injection of XIAFLEX into collagen-containing structures such as the corpora cavernosa of the penis may result in damage to those structures and possible injury such as corporal rupture (penile fracture). Therefore, XIAFLEX should be injected only into the Peyronie's plaque and care should be taken to avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis. Cases of localized skin and soft tissue necrosis occurring as sequelae of penile hematoma, some requiring surgical intervention, have been reported post-marketing
- **Hypersensitivity Reactions, Including Anaphylaxis:** In the double-blind, placebo-controlled portions of the clinical trials in Peyronie's disease, a greater proportion of XIAFLEX-treated patients (4%) compared to placebo-treated patients (1%) had localized pruritus after up to 4 treatment cycles (involving up to 8 XIAFLEX injection procedures). The incidence of XIAFLEX-associated pruritus was similar after each injection regardless of the number of injections administered
    - 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. The safety of more than one treatment course of XIAFLEX is not known
- **Risk of Bleeding in Patients with Abnormal Coagulation:** In the XIAFLEX controlled trials in Peyronie's disease, 65.5% of XIAFLEX-treated patients developed penile hematoma, and 14.5% developed penile ecchymosis. 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)
- **Acute Post-Injection Back Pain Reactions:** Post-marketing reports of acute lower back pain reactions, sometimes accompanied by radiation to the lower extremities, chest and arms, muscle spasms, chest pain, paresthesias, headache, and dyspnea, have been received by patients treated with XIAFLEX for Peyronie's disease. These events can be mild to severe in intensity. The events typically lasted for 15 minutes and typically did not require intervention.
  Administer the smallest number of treatment cycles necessary to treat the patient's curvature deformity
- **Syncope and Presyncope:** Most, but not all cases of syncope and presyncope in patients with Peyronie's disease, occurred in association with post-injection penile pain and hematoma, penile pain with spontaneous erections, and pain during micturition. These potential triggers suggest a vasovagal mechanism. Make patients aware of the potential symptoms that could trigger syncope and presyncope after treatment with XIAFLEX.
  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

Adverse Reactions

Clinical trials

- In the XIAFLEX clinical trials for Peyronie's disease, the most frequently reported adverse drug reactions (≥25%) and at an incidence greater than placebo included: penile hematoma, penile swelling, and penile pain.

Post-marketing experience

- Acute post-injection lower back pain reactions have occurred in close temporal proximity to XIAFLEX treatments
- Cases of localized skin and soft tissue necrosis events as sequelae of penile hematoma, some of which required surgical intervention
- Syncope and presyncope have been reported in men treated with XIAFLEX for Peyronie's disease. Most, but not all cases occurred in the immediate treatment period or within 1-2 days following injection. Bodily injuries associated with the syncopal events have been reported

Click for full Prescribing Information, including Boxed Warning and Medication Guide.

About Keenova

Keenova Therapeutics is a leading U.S.-focused branded therapeutics company that strives to help patients with rare or unaddressed conditions live happier and healthier lives.

Keenova's rare disease capabilities underpin our diversified brands portfolio, which is focused across a wide range of specialty therapeutic areas of significant unmet need. These include rheumatology, ophthalmology, nephrology, neurology, pulmonology, orthopedics, urology, and neonatal respiratory critical care.

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
This release contains forward-looking statements, including with regard to XIAFLEX, the efficacy, potential treatments or indications, therapeutic outcomes or treatment responses of this product, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of, and compliance with, regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; changes in market demand; issues with product quality, manufacturing or supply, or patient safety issues or adverse side effects or adverse reactions associated with XIAFLEX; and other risks identified and described in more detail in the "Risk Factors" and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Keenova's most recent Annual Reports on Form 10-K, and other filings and furnishings with the Securities and Exchange Commission (SEC), all of which are available from the SEC's website (www.sec.gov). The forward-looking statements made herein speak only as of the date hereof and we do 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.

* Based on a survey of about 7,700 U .S. adult men with a PD diagnosis, PD-related symptoms, or a history of seeking treatment for the condition.

References

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2. Stuntz M, Perlaky A, des Vignes F, et al. *PLoS One*. 2016;11(2):e0150157.
3. DiBenedetti DB, Nguyen D, Zografos L, et al. *Adv Urol*. 2011*;* 2011:282503.

Contacts

Media:	*Investors:*
media.relations@keenova.com	investor.relations@keenova.com

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