Keenova Advances Podiatry Pipeline with First Patient Dosed in Phase 3 Trial of XIAFLEX® (collagenase clostridium histolyticum) for Hammer Toe

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- *First registered, randomized Phase 3 trial evaluating the efficacy, safety, and tolerability of XIAFLEX in adults with hammer toe*
- *No FDA-approved nonsurgical therapies currently indicated for the treatment of hammer toe*
- *Hammer toe treatment today is limited to mainly orthotics, painkillers, or surgery*

DUBLIN, Aug. 20, 2026 /PRNewswire/ -- Keenova Therapeutics plc announced today that the first patient has been successfully enrolled and received study treatment in its Phase 3 clinical trial evaluating XIAFLEX® (collagenase clostridium histolyticum) as an investigational nonsurgical treatment for patients with hammer toe.

While conservative management and surgical intervention are available, there are currently no FDA-approved nonsurgical therapies indicated for the treatment of hammer toe.

"We are pleased to reach this important development milestone with the first patient dosed in our Phase 3 hammer toe study," said Dr. Marek Honczarenko, Executive Vice President and Chief Scientific Officer at Keenova. "This musculoskeletal condition can impair foot function and limit mobility, which may impact patients' quality of life. We believe XIAFLEX has the potential to address a significant unmet need for patients seeking a nonsurgical treatment approach and look forward to evaluating its clinical efficacy, safety, and tolerability in this pivotal study."

XIAFLEX is currently approved by the U.S. Food & Drug Administration for urological and orthopedic conditions. XIAFLEX is investigational for the treatment of hammer toe and has not been approved by the FDA for this indication.

About KN3835-313
The Phase 3 trial, KN3835-313, is a double-blind, randomized, placebo-controlled study designed to evaluate the efficacy, safety, and tolerability of XIAFLEX in the treatment of hammer toe.

The primary endpoint evaluates whether XIAFLEX improves the ability to straighten the affected toe by reducing the flexion contracture of the proximal interphalangeal (PIP) joint. Secondary objectives include changes in foot function, activity limitations, and participants' assessment of overall hammer toe severity.

The study is expected to enroll approximately 550 participants across an estimated 35 sites in the United States.

This study is registered on ClinicalTrials.gov under the identifier NCT07759362.

About Hammer Toe
Hammer toe is a foot deformity in which one or more toes, most commonly the second toe, bend downward at the middle joint due to flexion, or contracture, of the proximal interphalangeal (PIP) joint, creating a hammer-like appearance.[1,2] The musculoskeletal condition is more common in women and is frequently seen in adults, particularly older adults.[2,3] The condition is driven by muscle-tendon imbalance, trauma, and external factors such as ill-fitting footwear, including narrow or high-heeled shoes.[1,2] Symptoms can include pain, discomfort, and difficulty walking.[1,2] Current treatment options range from conservative approaches such as footwear modification, orthoses, and exercises or physical therapy, to surgical correction in more advanced cases.[1,2] Hammer toe is one of the most common lesser toe deformities,[4] though prevalence estimates vary greatly in scientific literature. Based on claims data, approximately 2 million adults in the U.S. were diagnosed with hammer toe in 2025.*

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, safety, potential treatments or indications, and therapeutic outcomes or treatment responses of this investigational nonsurgical treatment for patients with hammer toe, 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.

* Data on file. Analysis of de-identified U.S. medical and pharmacy claims data from Komodo Health, 2025.

References

1. American Academy of Orthopaedic Surgeons. *Hammer Toe: Comprehensive Guide*. OrthoInfo. Accessed July 16, 2026. https://www.orthoinfo.org/diseases--conditions/hammer-toe/
2. American Podiatric Medical Association. *Hammer Toes*. APMA. Accessed July 16, 2026. https://www.apma.org/patients-and-the-public/conditions-affecting-the-foot-and-ankle/hammer-toes/
3. Mayo Clinic Staff. Hammertoe and mallet toe: Symptoms and causes. Mayo Clinic. Accessed July 21, 2026. https://www.mayoclinic.org/diseases-conditions/hammertoe-and-mallet-toe/symptoms-causes/syc-20350839
4. Hagedorn TJ, Dufour AB, Riskowski JL, et al. Foot Disorders, Foot Posture, and Foot Function: The Framingham Foot Study. *PLoS One*. 2013;8(9):e74364.

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