Keenova Announces Positive Phase 3 Results in Clinical Trial of XIAFLEX® (collagenase clostridium histolyticum) for Treating Plantar Fibromatosis

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DUBLIN, July 8, 2026 /PRNewswire/ -- Keenova Therapeutics plc announced today positive results from its Phase 3 clinical trial of XIAFLEX® (collagenase clostridium histolyticum) for the treatment of plantar fibromatosis, a chronic medical condition that causes nodules composed primarily of excess collagen to form in the connective tissue that supports the arch of the foot.

The Results

- The pivotal trial met the primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in pain versus placebo, as measured by the Average Daily Pain Intensity on the Numeric Rating Scale (NRS).
- It also met key ranked secondary endpoints related to difficulty and activity limitation as measured by the Foot Function Index (FFI) scale.
- The treatment benefit observed on the primary pain endpoint and key functional secondary endpoints was further supported by statistically significant improvements in additional secondary measures, including the FFI pain subscale, global assessments of improvement and disease severity, treatment satisfaction, and nodule characteristics.
- The safety profile of XIAFLEX in this study was consistent with the known safety profile of XIAFLEX from approved indications. Most adverse events were rated by the investigators as mild to moderate and there were no treatment-related serious adverse events.

"We are excited to share the positive outcome for our Phase 3 clinical trial of plantar fibromatosis, a disease for which limited treatment options exist beyond symptom relief measures or surgery," said Dr. Marek Honczarenko, Executive Vice President and Chief Scientific Officer at Keenova. "With these encouraging results, we intend to submit our application for this indication to the FDA in the fourth quarter of 2026 as part of an effort to expand our XIAFLEX portfolio and help address unmet patient needs."

Based on claims data and projections, the company believes about 300,000 people will see a healthcare provider for their plantar fibromatosis in 2028, when Keenova expects to launch XIAFLEX for the indication.

XIAFLEX is currently approved by the U.S. Food & Drug Administration for urological and orthopedic conditions.

About EN3835-309 PFI
EN3835-309 was a double-blind, placebo-controlled Phase 3 trial to assess the overall reduction in the intensity of foot pain of XIAFLEX in the treatment of plantar fibromatosis.

The pivotal trial enrolled 436 participants with plantar fibromatosis and at least one measurable, hard or firm, palpable fibrous nodule on clinical examination. Participants were randomly assigned to one of two treatment groups, with one group receiving XIAFLEX and the other receiving placebo. Each group received up to two treatments, with each treatment separated by a minimum of 28 days.

Participants captured pain intensity on the Numeric Rating Scale (NRS) each day, and during several pre-determined follow-up visits, they completed additional questionnaires—including Subject Satisfaction With Treatment, Foot Function Index (FFI), Patient Global Impression of Severity (PGIS), and Patient Global Impression of Change (PGIC)—to report measures related to disability and activity limitation.

About Plantar Fibromatosis
Plantar fibromatosis, or Ledderhose disease, is a hyperproliferative fibrous tissue disorder resulting in the formation of collagen nodules along the plantar fascia, the thick connective tissue that supports the arch of the foot. The condition is chronic and progressive, leading to pain, walking impairment, and reductions in quality of life. There currently are no approved pharmacological treatments for plantar fibromatosis. Symptom management options include custom insoles (orthotics), topical treatments, over-the-counter pain and anti-inflammatory medications, radiation therapy, steroid injections, and, ultimately, surgery may be required to remove the nodules.

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.

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