Keenova Announces Publication of New Acthar® Gel (repository corticotropin injection) Manuscript in the Journal of Comparative Effectiveness Research

July 13, 2026

DUBLIN, July 13, 2026 /PRNewswire/ -- Keenova Therapeutics plc announced the publication of a new manuscript about the use of Acthar Gel (repository corticotropin injection) to treat certain severe autoimmune diseases. Sponsored by Keenova, the retrospective, physician-reported, survey-based medical chart review study covered in the manuscript used real-world clinical data to evaluate patient characteristics, treatment patterns, and physicians' assessments of outcomes among individuals with rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), and dermatomyositis/polymyositis (DM/PM) who received Acthar Gel. The manuscript appears in the peer-reviewed *Journal of Comparative Effectiveness Research* and is available here.

Please see indications and Important Safety Information for Acthar Gel below.

"Real-world evidence for Acthar Gel in RA, SLE, or DM/PM has been limited. This manuscript helps clarify how clinicians are using Acthar Gel in complex, often treatment-refractory cases," said George J. Wan, Vice President, Evidence, Value & Outcomes at Keenova and senior author of the study. "These findings add to the available data evaluating Acthar Gel as an option for appropriate patients."

"Patients with severe autoimmune diseases deserve access to every effective therapy that can improve their quality of life," said Dr. Marek Honczarenko, Executive Vice President and Chief Scientific Officer at Keenova. "Acthar Gel remains a real option for eligible patients who have not responded to previous treatments, and we are committed to advancing the science behind this therapeutic."

Manuscript Details

- **Title:** Acthar Gel treatment in patients with rheumatoid arthritis, systemic lupus erythematosus, or dermatomyositis/polymyositis: Analysis of physician-reported charts
- **Authors:** Kyle Hayes, MS; Amit Patel, PhD; Priyanka P. Shanbhag, MS; Destri R. Evans, MBA; Mary Prince Panaccio, PhD; Johanna Purcell, PhD; George J. Wan, PhD, MPH

About Rheumatoid Arthritis
Rheumatoid arthritis (RA) is a chronic autoimmune disease in which the immune system mistakenly attacks the lining of the joints. This inflammation leads to pain, stiffness, swelling, and progressive joint damage. An estimated 1.5 million adults in the U.S. are living with RA.[1]

About Systemic Lupus Erythematosus
Systemic lupus erythematosus (SLE) is the most common type of lupus. It's a chronic inflammatory condition that may affect joints, skin, and kidneys. No two cases are the same, and symptoms can vary widely and change over time.[2] In the U.S., an estimated 160,000 to 260,000 adults are affected by SLE.[3]

About Dermatomyositis/Polymyositis
Dermatomyositis and polymyositis (DM/PM) are rare inflammatory diseases that cause progressive muscle weakness,[4] with the former also causing characteristic skin rashes and the latter primarily affecting the muscles closest to the trunk of the body.[5] People of all ages can be affected, though DM and PM most often occur between ages 40 and 60 and are more common in women.[6]

INDICATIONS

Acthar Gel is indicated for:

- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis)

- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- Treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- Symptomatic sarcoidosis

IMPORTANT SAFETY INFORMATION

Contraindications

Acthar is contraindicated:

- For intravenous administration
- In infants under 2 years of age who have suspected congenital infections
- With concomitant administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of Acthar
- In patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin

Warnings and Precautions

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-adrenal (HPA) axis may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g., trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA axis suppression after stopping treatment
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Monitor blood pressure and sodium and potassium levels
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause gastrointestinal (GI) bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain GI disorders. Monitor for signs of perforation and bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression to psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma, and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Cases of anaphylaxis have been reported in the postmarketing setting. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH and Acthar activity
- There may be an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored in patients on long-term therapy

Adverse Reactions

- Commonly reported postmarketing adverse reactions for Acthar include injection site reaction, asthenic conditions (including fatigue, malaise, asthenia, and lethargy), fluid retention (including peripheral swelling), insomnia, headache, and blood glucose increased
- The most common adverse reactions for the treatment of infantile spasms (IS) are increased risk of infections, convulsions, hypertension, irritability, and pyrexia. Some patients with IS progress to other forms of seizures; IS sometimes masks these seizures, which may become visible once the clinical spasms from IS resolve

Pregnancy

- Acthar may cause fetal harm when administered to a pregnant woman

Please see full Prescribing Information for additional Important Safety Information.

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 ACTHAR® Gel, its potential to improve health and treatment outcomes, and its potential impact on patients. 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 ACTHAR Gel; and other risks and uncertainties identified and described in more detail in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Keenova's most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, filed with the Securities and Exchange Commission (SEC) and other filings with the SEC, all of which are available on the SEC's website (www.SEC.gov) and our website (www.keenova.com). The forward-looking statements made herein speak only as of the date hereof and Keenova Therapeutics 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

1. Arthritis Foundation. Rheumatoid Arthritis: Causes, Symptoms, Treatments and More. Accessed June 2026. https://www.arthritis.org/diseases/rheumatoid-arthritis
2. Lupus Research Alliance. About Lupus. Accessed June 2026. https://www.lupusresearch.org/understanding-lupus/what-is-lupus/about-lupus/
3. Izmirly PM, Parton H, Wang L, et al. Prevalence of systemic lupus erythematosus in the United States: estimates from a meta-analysis of the Centers for Disease Control and Prevention National Lupus Registries. *Arthritis Rheumatol.* 2021;73(6):991-996. doi:10.1002/art.41632.
4. Mayo Clinic. Polymyositis. Available at: http://www.mayoclinic.org/diseases-conditions/polymyositis/basics/symptoms/con-20020710. Accessed June 2026.
5. Medline Plus. Myositis. Available at: https://medlineplus.gov/myositis.html. Accessed June 2026.
6. Bernatsky S, Joseph L, Pineau CA, et al. Estimating the prevalence of polymyositis and dermatomyositis from administrative data: age, sex and regional differences. *Ann Rheum Dis*. 2009;68(7):1192-1196.

Contacts

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

View original content to download multimedia:https://www.prnewswire.com/news-releases/keenova-announces-publication-of-new-acthar-gel-repository-corticotropin-injection-manuscript-in-the-journal-of-comparative-effectiveness-research-302823077.html

SOURCE Keenova Therapeutics