Mallinckrodt Announces Publication of Real-World Insights on Patient Experience with Acthar® Gel (repository corticotropin injection) Single-Dose Pre-filled SelfJect™ Injector

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– Survey findings showed a majority of participants had a favorable experience injecting Acthar Gel via SelfJect, with a high level of satisfaction, confidence, convenience, and ease of use regarding the injector[1] –

DUBLIN, June 18, 2025 /PRNewswire/ -- Mallinckrodt plc, a global specialty pharmaceutical company, today announced the publication of findings from a survey assessing patient perceptions of their experience with Acthar® Gel (repository corticotropin injection) Single-Dose Pre-filled SelfJect™ Injector ("SelfJect"). SelfJect is a single-dose pre-filled injector designed for the administration of Acthar Gel in appropriate patients.[2] It is approved by the U.S. Food and Drug Administration (FDA) for patients with a range of chronic and acute inflammatory conditions.[2] The survey collected data on patient perceptions of satisfaction, confidence, convenience, and ease of use, as well as perceptions of anticipated persistence and compliance.[1] The manuscript was recently published online in *Advances in Therapy*.

Acthar Gel is a naturally sourced complex mixture of adrenocorticotropic hormone (ACTH) analogs and other pituitary peptides.[2] Acthar Gel is approved by the FDA for the treatment of several autoimmune disorders and medical conditions known to cause inflammation.[2] SelfJect is available in 40 USP units/0.5 mL and 80 USP units/1.0 mL injectors and must be administered by adults (18 years of age or older).[2] SelfJect is not to be used for the treatment of infantile spasms.[2]

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

"Real-world perceptions are critical to capturing patient satisfaction and treatment experience with SelfJect beyond clinical trials, especially for those living with conditions that can often be challenging to manage," said **George Wan, Ph.D., M.P.H., Vice President, Evidence Generation and Data Sciences, Mallinckrodt.** "Findings from this cross-sectional patient survey enhance our understanding on the use of Acthar Gel via SelfJect in appropriate patients."

"Patients, particularly those with chronic or acute inflammatory and autoimmune conditions who may experience dexterity and/or visual challenges, need access to delivery devices they feel are easy and convenient to use," said **Steven Taylor, President and CEO, Arthritis Foundation**. "This is why rigorous, independent evaluation is required for products and packaging to earn our Ease of Use® certification. We appreciate the work of organizations like Mallinckrodt, whose dedication to advancing therapies drives meaningful progress for people impacted by these conditions."

About the Survey

"Real-World Insights on Patient Satisfaction and Experience with Acthar Gel via SelfJect (RISE™): ACross-Sectional Patient Survey" utilized a validated form and was conducted among a cross-section of patients to assess their experience with SelfJect.[1] The survey, conducted between November 2024 and January 2025, collected data from 54 participants with a mean age of 55.4 years.[1] The majority of participants were female 76% (n=41/54), and identified as White/Caucasian 74% (n=40/54) and non-Hispanic/non-Latino 83% (n=45/54).[1] Eligible participants were aged ≥18 years, had a diagnosis of an indication of Acthar Gel based on the prescribing information, and had used Acthar Gel via SelfJect for ≥6 self-injections at the time of the survey.[1] Additionally[1]:

- 33% (n=18/54) reported chronic or recurring ocular inflammatory disease, and 26% (n=14/54) had rheumatoid arthritis
- 39% (n=21/54) reported dexterity or visual problems
- 39% (n=21/54) reported having previously used Acthar Gel multi-dose vial and syringe

In this survey, participants reported a favorable experience injecting Acthar Gel via SelfJect, highlighting high levels of satisfaction, confidence, convenience, and ease of use regarding the injector.[1] Participants also reported perceptions of anticipated positive persistence and compliance with the device, which may correlate with improved continuity of care.[1] Findings from this survey included[1]:

- 91% (n=49/54) reported they were satisfied or very satisfied injecting Acthar Gel via SelfJect overall
- 89% (n=48/54) felt very or extremely confident administering Acthar Gel via SelfJect to themselves at home
- 91% (n=49/54) found SelfJect to be convenient or very convenient
- 100% (n=54/54) felt that it was moderately, very or extremely easy to self-inject with SelfJect
- 87% (n=47/54) responded that they were likely or very likely to continue taking Acthar Gel via SelfJect for the prescribed period, and 87% (n=47/54) also responded that they were likely or very likely to maintain compliance for the prescribed period, with respect to timing, dosage, and frequency

Summary of limitations of the survey include[1]:

- Data collected from the questionnaire are cross-sectional and do not provide long-term information on patient satisfaction.
- Persistence and compliance were assessed based on participant perceptions rather than objective, longitudinal measurement. Future research using longitudinal designs is needed to evaluate these factors accurately.
- Response bias may be present as the findings rely on survey participants' subjective experiences with the device.
- This descriptive study characterizes the experience of survey participants with an alternative delivery device; therefore, it does not include direct comparisons of Acthar Gel via SelfJect with other self-injection devices.

This survey was sponsored by Mallinckrodt Pharmaceuticals.

INDICATIONS

Acthar Gel is indicated for:

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis) and systemic lupus erythematosus
- 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
- Symptomatic sarcoidosis
- 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
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- 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
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age

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 Mallinckrodt
Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The Company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology and ophthalmology; neonatal respiratory critical care therapies; and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS
This release contains forward-looking statements, including with regard to Acthar Gel (repository corticotropin injection), the Acthar Gel Single-Dose Pre-filled SelfJect™ Injector, the potential of these products to improve health and treatment outcomes, and their 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: the effects of Mallinckrodt's recent emergence from bankruptcy; 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 Acthar Gel Single-Dose Pre-filled SelfJect Injector; and other risks 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 Mallinckrodt's most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on its website. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt 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.

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[1] Bindra J., Chopra I., Hayes K., et al. Real-World Insights on Satisfaction and Experience with Acthar Gel via SelfJect (RISE™): A Cross-Sectional Patient Survey. *Advances in Therapy*. 2025. https://doi.org/10.1007/s12325-025-03232-5.

[2] Acthar® Gel (repository corticotropin injection) [Prescribing Information]. Bridgewater, NJ: Mallinckrodt ARD LLC.

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