



## Mallinckrodt to Present New Retrospective Data on Effect of Acthar® Gel (Repository Corticotropin Injection) to Reduce Corticosteroid Use and Burden for Advanced Sarcoidosis at the Academy of Managed Care Pharmacy (AMCP) 2023 Annual Meeting

March 21, 2023

- Findings from a retrospective analysis suggest that treatment with Acthar Gel is associated with significant reductions in corticosteroid use compared to other fourth-line alternatives for patients with advanced sarcoidosis<sup>1</sup> –

DUBLIN , March 21, 2023 /PRNewswire/ -- [Mallinckrodt plc](#) (NYSE American: MNK), a global specialty pharmaceutical company, today announced that an abstract highlighting results from a retrospective analysis evaluating the corticosteroid-sparing effect and reduction of corticosteroid burden of Acthar® Gel (repository corticotropin injection) therapy in patients with advanced sarcoidosis,<sup>1</sup> has been selected for [a poster presentation](#) at the Academy of Managed Care Pharmacy (AMCP) 2023 Annual Meeting taking place in San Antonio, Texas from March 21-24, 2023.



Acthar Gel is a naturally sourced complex mixture of adrenocorticotrophic hormone analogs and other pituitary peptides. Acthar Gel is approved by the U.S. Food and Drug Administration (FDA) for the treatment of symptomatic sarcoidosis and is only commercially available in the U.S.<sup>2</sup> Acthar Gel is also referenced in the European Respiratory Society (ERS) treatment guidelines—which list Acthar Gel among the various anti-inflammatory treatments for pulmonary sarcoidosis and note it can be used on a case-by-case basis when other therapies are ineffective or not tolerated—and a U.S. expert panel provided consensus recommendations on the use of repository corticotropin injection for the treatment of pulmonary sarcoidosis.<sup>3,4</sup>

### **Please see Important Safety Information for Acthar Gel below.**

The retrospective analysis used data from a large administrative pharmacy and medical claims database (Symphony Health Solutions), including a total of 1,361 sarcoidosis patients (n=735 for Acthar Gel cohort; n=626 for alternative fourth-line cohort) from 2014-2020. Outcomes were compared as change from baseline and Acthar Gel adherence was determined by proportion of days covered in the follow-up period. The analysis found that, after treatment with Acthar Gel, patients had greater reduction from baseline in any corticosteroid fills (-9.0% vs. -3.2%) and extended use corticosteroid fills (-10.0% vs. -3.0%) compared to those receiving fourth-line treatment, with Acthar Gel above average adherence showing greater reduction than below-average adherence in both measures (-11.2% vs. -6.1%; -11.6% vs. -7.6% respectively).<sup>1</sup>

**George J. Wan, Ph.D., M.P.H., Vice President Health Economics and Outcomes Research at Mallinckrodt**, said, "We're excited to share these data that not only provide valuable insight into the association between use of Acthar Gel and reduction in corticosteroid use, but also reinforce the importance of treatment adherence to help improve outcomes for patients with advanced sarcoidosis.<sup>1</sup> We remain committed to addressing the unmet needs of critically ill patient populations and are proud to continue the collection of real-world data to help inform patients' treatment options."

In this retrospective analysis, patients treated with Acthar Gel also had significantly greater reduction of extended corticosteroid use at all dose levels compared to fourth-line treatment, with Acthar Gel above average adherence reduction better than below average (-9.5% vs. -5.7% for medium corticosteroid dose; -10.0% vs. -8.6% for high corticosteroid dose, respectively).<sup>1</sup>

Data collected in a retrospective analysis may have errors or omissions. Outcomes may be influenced by therapies not evaluated in the study and the clinical outcomes may not be solely attributable to Acthar.

This study was funded by Mallinckrodt Pharmaceuticals. Presentation details are as follows:

**Presentation Title:** Corticosteroid use and adherence in patients treated with Acthar Gel for advanced sarcoidosis

**Presenter:** Kyle Hayes, MS

**Presentation Date:** Thursday, March 23, 2023, at 11:30am – 1:00pm CT / 12:30pm – 2:00pm ET

**Location:** Henry B. Gonzalez Convention Center, Hall 2

Additional information is available on the [Academy of Managed Care Pharmacy \(AMCP\) 2023 Annual Meeting](#) website.

### **About Sarcoidosis**

Sarcoidosis is a challenging and rare multisystem disease.<sup>5,6</sup> In some cases the symptoms may come and go throughout one's lifetime. This is referred to as symptomatic sarcoidosis. In people living with sarcoidosis, the immune system overreacts, forming clumps of cells called granulomas that result in inflammation of the body's tissues.<sup>7</sup> The disease can impact any organ but most often impacts the lungs, lymph nodes, eyes, and skin.<sup>5</sup> Over 90% of people with sarcoidosis suffer lung problems.<sup>5,8</sup> Concomitant involvement of organs outside of the lungs is common, occurring in as many as half of all sarcoidosis cases.<sup>8</sup>

### **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 or 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 post marketing 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 post marketing 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, ophthalmology, and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes 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](http://www.mallinckrodt.com).

Mallinckrodt 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.

## CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

This release includes forward-looking statements concerning Acthar Gel® (repository corticotropin injection), including its potential impact on patients and anticipated benefits associated with its use, as well as related on-going studies. 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 regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; issues with product quality, manufacturing or supply, or patient safety issues; and other risks identified and described in more detail in the "Risk Factors" section 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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## References

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<sup>1</sup> Hayes K, et al. Corticosteroid use and adherence in patients treated with Acthar Gel for advanced sarcoidosis. *Abstract to be presented at Academy of Managed Care Pharmacy (AMCP) 2023 Annual Meeting*. March 2023.

<sup>2</sup> Acthar® Gel (repository corticotropin injection) [prescribing information]. Mallinckrodt ARD LLC.

<sup>3</sup> Baughman RP, Valeyre D, Korsten P, et al. ERS clinical practice guidelines on treatment of sarcoidosis. *Eur Respir J*. 2021; in press ([doi.org/10.1183/13993003.04079-2020](https://doi.org/10.1183/13993003.04079-2020))

<sup>4</sup> Rahaghi FF, Sweiss NJ, Saketkoo LA, et al. Management of repository corticotrophin injection therapy for pulmonary sarcoidosis: a Delphi study. *Eur Respir Rev*. 2020; 29:190147. [doi.org/10.1183/16000617.0147-2019](https://doi.org/10.1183/16000617.0147-2019).


<sup>5</sup> Judson MA. The clinical features of sarcoidosis: a comprehensive review. *Clin Rev Allerg Immunol*. 2015;49:63-78.

<sup>6</sup> Baughman RP, Field S, Costabel U, et al. Sarcoidosis in America. Analysis based on health care use. *Ann Am Thorac Soc*. 2016;13:1244-1252.

<sup>7</sup> Baughman RP, Culver DA, Judson MA. A concise review of pulmonary sarcoidosis. *Am J Respir Crit Care Med*. 2011;183:573-581.

<sup>8</sup> Shigemitsu H, Patel HV, Schreiber MP. Extrapulmonary sarcoidosis. In: Judson MA, ed. *Pulmonary Sarcoidosis: A Guide for the*

Practicing Clinician. Vol 17. New York, NY: Springer; 2014:149-186.

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