Mallinckrodt Announces U.S. FDA Approval of Supplemental New Drug Application for Acthar® Gel (repository corticotropin injection) Single-Dose Pre-filled SelfJect™ Injector

March 1, 2024

– Acthar Gel Single-Dose Pre-filled SelfJect Injector is a self-controlled, pre-filled delivery device[1] for appropriate patients with a range of chronic and acute inflammatory and autoimmune conditions[2] –

– This first-in-class delivery device reduces the steps required for patients and caregivers to administer Acthar Gel treatment[1] and underscores Mallinckrodt's mission by advancing Acthar Gel therapeutic modernization efforts to address patient needs –

– Acthar Gel Single-Dose Pre-filled SelfJect Injector is expected to launch in the U.S. in the second half of 2024 –

DUBLIN, March 1, 2024 /PRNewswire/ -- Mallinckrodt plc, a global specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved Mallinckrodt's supplemental New Drug Application (sNDA) for the Acthar® Gel (repository corticotropin injection) Single-Dose Pre-filled SelfJect™ Injector (herein referred to as "SelfJect"), a new delivery device for Acthar Gel for appropriate patients with a range of chronic and acute inflammatory and autoimmune conditions.[2] SelfJect is intended to provide the appropriate subcutaneous dose of Acthar Gel, as prescribed by a healthcare professional, and is designed to help give patients control of their administration.[1,3]

Acthar Gel is a naturally sourced complex mixture of adrenocorticotropic hormone analogs and other pituitary peptides.[2] Acthar Gel is approved by the U.S. FDA for the treatment of several autoimmune disorders and medical conditions known to cause inflammation.[2]

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

"We're excited to bring this innovation to U.S. patients with chronic and acute inflammatory and autoimmune conditions. This approval reflects Mallinckrodt's longstanding commitment to clinical research and therapeutic modernization efforts providing a new delivery device for patients, caregivers, and medical professionals managing these challenging conditions," said **Peter Richardson, MRCP (UK), Executive Vice President and Chief Scientific Officer**.

With this approval, Acthar Gel is the first in its class of medications to offer a self-controlled, pre-filled delivery device for appropriate patients with a range of chronic and acute inflammatory and autoimmune conditions.[1,2] SelfJect may allow patients to self-administer Acthar Gel with fewer steps, as prescribed by a healthcare professional.[1] The delivery device is pre-filled with the prescribed dose of Acthar Gel in 40-unit or 80-unit versions,[1] is designed to help patients with dexterity issues,[4] and has additional safety features including a hidden needle to help protect patients against needlestick injury.[3]

Acthar Gel has an established efficacy and safety profile, as well as a long track record of clinical experience spanning more than 70 years.[2] Acthar Gel has been prescribed by over 9,200 healthcare professionals and used by more than 43,500 patients.[5]

Mallinckrodt is committed to providing therapy for appropriate patients with difficult-to-treat conditions. Mallinckrodt offers a suite of services for eligible Acthar Gel patients including support with insurance coverage, commercial copay assistance, a patient assistance program, injection training services, and customized assistance by a nurse navigator. Mallinckrodt also offers a team of field-based experts who provide education for healthcare professionals on the reimbursement process as well as tools available for patients. For more information about Mallinckrodt's programs and patient support please visit ActharHCP.com.

SelfJect is expected to launch in the U.S. in the second half of 2024. Acthar Gel will continue to be available as an injection with a vial and syringe.

INDICATIONS

Acthar Gel is indicated for:

- 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
- 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 dermatomyositis (polymyositis)
- 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

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

theses 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; 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, the Acthar® Gel (repository corticotropin injection) Single-Dose Pre-filled SelfJect™ Injector, the potential of these products to improve health and treatment outcomes, their potential impact on patients and the availability of Acthar Gel Single-Dose Pre-filled SelfJect Injector in the U.S. in the future. 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" 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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[1] Data on file – ref-05469. Mallinckrodt Pharmaceuticals, Inc.
[2] Acthar® Gel (repository corticotropin injection) [prescribing information]. Mallinckrodt ARD LLC. 2024.
[3] Data on file – ref-05573. Mallinckrodt Pharmaceuticals, Inc.
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