



ANI Pharmaceuticals Announces Presentation of Preclinical Data on the Use of Purified Cortrophin® Gel in an Experimental Autoimmune Uveitis (EAU) Mouse Model

May 5, 2025

Demonstrated Dose Dependent Effect in EAU

Presented in a podium presentation at The Association for Research in Vision and Ophthalmology (ARVO) 2025 annual meeting

PRINCETON, N.J., May 05, 2025 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced preclinical data on the use of Purified Cortrophin® Gel (repository corticotropin injection USP) (Cortrophin Gel) in an EAU mouse model.

"In a preclinical model of autoimmune uveitis, Cortrophin Gel reduced levels of inflammatory molecules without stimulating an adverse immune response," said Mary Pao, MD, PhD, Chief Medical Officer of Rare Disease at ANI. "The results further support our understanding of Cortrophin Gel's mechanism of action."

An experimental autoimmune uveitis (EAU) mouse model was used to determine the impact of four doses (4, 40, 160 or 400 U/kg) of repository corticotropin injection (RCI, an equivalent to Cortrophin Gel in this model). The results showed a significant dose-dependent effect on the suppression of EAU at all doses, with the greatest suppression of EAU at the 400 U/kg dose. RCI also significantly suppressed the production of cytokines implicated in inflammation and immune system activation. Additionally, 400 U/kg Purified Cortrophin Gel treatment suppressed retinal damage caused by EAU, similar to α -MSH treatment, compared to placebo.

"The data presentation at ARVO is part of ANI's broader commitment to clinical research for our products and, specific to Cortrophin Gel, we are committed to building on the scientific evidence and clinical data supporting its mechanism of action and clinical use," said Nikhil Lalwani, President and Chief Executive Officer at ANI.

The data were presented yesterday in a podium presentation by Andrew W. Taylor, PhD at The Association for Research in Vision and Ophthalmology (ARVO) 2025 annual meeting being held May 4-8, 2025 in Salt Lake City, UT. Dr. Taylor is the Sarkis J. Kechejian Professor; Associate Dean of Research; and Professor & Vice-Chair of Research, Department of Ophthalmology at Boston University Chobanian & Avedisian School of Medicine.

Presentation Title: The Therapeutic Effects of Purified Cortrophin® Gel on Experimental Autoimmune Uveitis

Session Title: Innovative Strategies For Modulating Ocular Inflammation

Presentation #: 896

Presentation Time: Sunday, May 4, 2025 from 4:45 PM to 5:00 PM

Lead Author: Andrew W. Taylor, PhD

The abstract and presentation are available online at <https://www.arvo.org/annual-meeting/>.

About Uveitis

Uveitis is an inflammatory condition affecting the uvea, the middle layer of the eye.

Indication

Cortrophin Gel is a prescription medicine that is injected subcutaneously or intramuscularly. It is indicated for:

- Severe acute and chronic allergic and inflammatory conditions affecting the eye and its adnexa, such as allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.

Important Safety Information

Contraindications

- Cortrophin Gel is contraindicated for intravenous administration.
- Cortrophin Gel is contraindicated in patients who have any of the following conditions: scleroderma; osteoporosis; systemic fungal infections; ocular herpes simplex; recent surgery; history of or the presence of a peptic ulcer; congestive heart failure; hypertension; primary adrenocortical insufficiency; adrenocortical hyperfunction; or sensitivity to proteins derived from porcine sources.

Warnings and Precautions

- **Infections:** Corticotropin therapy may increase susceptibility to infections and may mask the symptoms of infections.
- **Adrenal insufficiency:** Prolonged corticotropin therapy can increase the potential for adrenal insufficiency after withdrawal

of the medication. Adrenal insufficiency may be minimized by gradually reducing the corticotropin dosage. Hormone therapy should be reinstated if stressful situations arise during discontinuation.

- **Elevated blood pressure, salt and water retention, and hypokalemia:** Corticotropin can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium or calcium.
- **Masking symptoms of other diseases:** Corticotropin may only suppress signs and symptoms of chronic disease without altering the natural course of disease.
- **Psychiatric reactions:** Psychic derangements may appear when corticotropin is used, ranging from euphoria, insomnia, mood swings, personality changes, and depression to psychosis. Existing conditions may be aggravated.
- **Ophthalmic reactions:** Prolonged use of corticotropin may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves.
- **Immunogenicity potential:** Prolonged administration of Cortrophin Gel may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH and Cortrophin Gel activity.
- **Vaccination:** Patients should not be vaccinated against smallpox while on corticotropin therapy. Other immunizations should be undertaken with caution due to possible neurologic complications and lack of antibody response.
- **Use in patients with hypothyroidism and cirrhosis:** There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis.
- **Use in patients with latent tuberculosis or tuberculin reactivity:** Closely observe for reactivation of the disease.
- **Comorbid diseases:** Corticotropin should be used with caution in patients with diabetes, abscess, pyogenic infections, diverticulitis, renal insufficiency, and myasthenia gravis.
- **Growth and development:** Carefully observe growth and development of infants and children on prolonged corticotropin therapy.
- **Acute gouty arthritis:** Treatment of acute gouty arthritis should be limited to a few days. Conventional concomitant therapy should be administered during corticotropin treatment and for several days after it is stopped.
- **Drug interactions:** Aspirin should be used cautiously with corticotropin in hypoprothrombinemia.
- **Pregnancy:** Since fetal abnormalities have been observed in animals, Cortrophin Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adverse Reactions

Adverse reactions for Cortrophin Gel include fluid or sodium retention; muscle weakness; osteoporosis; peptic ulcer with possible perforation and hemorrhage; injection site reactions; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; suppression of growth in children; and weight gain. These are not all the adverse reactions reported with Cortrophin Gel.

Please see full [Prescribing Information](#).

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified biopharmaceutical company committed to its mission of "Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high-quality therapeutics. The Company is focused on delivering sustainable growth through its Rare Disease business, which markets novel products in the areas of ophthalmology, rheumatology, nephrology, neurology, and pulmonology; its Generics business, which leverages R&D expertise, operational excellence, and U.S.-based manufacturing; and its Brands business. For more information, visit www.anipharmaceuticals.com.

Forward-Looking Statements

This press release contains not only historical information, but also forward-looking statements made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements represent the Company's expectations or beliefs concerning future events, including statements regarding the benefits of the acquisition of Alimera Sciences. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "continue," "strategy," "future," "opportunity," "plan," "may," "should," "will," "shall," "would" other words of similar meaning, derivations of such words and the use of future dates. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties.

The following factors, among others, could cause actual results to differ materially from those described in these forward-looking statements: the ability of our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability; our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the acquisition of Alimera, in a timely manner or at all; the limitation of our cash flow as a result of the indebtedness and liabilities incurred from the recent acquisition of Alimera; the risks that our acquisitions and investments, including the acquisition of Alimera, could disrupt our business and harm our financial position and operating results; delays and disruptions in production of our approved products, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients, excipients, and other materials; delays and disruptions in production of our approved products as a result of our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel, ILUVIEN and YUTIQ; delays or failure in obtaining and maintaining approvals by the FDA of the products we sell; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration and other regulatory agencies, and the focus of the current U.S. presidential administration, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions; risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; the ability of our manufacturing partners to meet our product demands and timelines;

the impact of changes or fluctuations in exchange rates; our ability to develop, license or acquire, and commercialize new products; our obligations in agreements under which we license, develop or commercialize rights to products or technology from third parties and our ability to maintain such licenses; the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products; our ability to protect our intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which we are, or may become, a party; our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; our ability to maintain the services of our key executives and other personnel; and general business and economic conditions, such as inflationary pressures, geopolitical conditions including but not limited to the conflict between Russia and the Ukraine, the conflict in the Middle East, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies. More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission ("SEC"), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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