ANI Pharmaceuticals Announces Initiation of Phase 4 Clinical Trial of Purified Cortrophin® Gel for the Treatment of Acute Gout Flares

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Purified Cortrophin Gel is the only ACTH therapy approved by the FDA for the treatment of acute gout flares

Trial to be conducted by Dr. Hyon Choi at Massachusetts General Hospital and will compare the safety and efficacy of two dose levels of Purified Cortrophin Gel for the treatment of acute gout flares

PRINCETON, N.J., May 22, 2025 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (ANI or the Company) (Nasdaq: ANIP) today announced the initiation of a Phase 4 clinical trial at Massachusetts General Hospital to compare the safety and efficacy of two dose levels (40 USP units and 80 USP units) of Purified Cortrophin Gel (repository corticotropin injection USP) (Cortrophin Gel) for the treatment of acute gout flares. Cortrophin Gel is indicated for short-term administration as an adjunctive therapy during an acute episode or exacerbation in acute gouty arthritis. Cortrophin Gel is contraindicated for intravenous administration. For additional important safety information, please see below.

“Gout is a chronic disease that affects millions of patients, including acute flares that can cause extreme pain and temporary disability,” said Hyon Choi, MD, DrPH, principal investigator of the study and clinical investigator and physician in the Rheumatology Unit at Mass General Research Institute/Massachusetts General Hospital (MGH). “For some patients, conventional anti-inflammatory treatments do not provide adequate relief from these flares. We look forward to initiating this dose-ranging study, which we believe will provide valuable scientific information about Cortrophin Gel in the treatment of acute gout flares.”

Dr. Choi has been a leading physician investigator with a primary focus on gout and other inflammatory arthritic conditions throughout his academic career. He has authored more than 150 gout-related peer-reviewed papers in leading journals, and his findings have been referenced by many articles as well as guidelines from the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR). Dr. Choi directs the MGH Gout & Crystal Arthropathy Center and co-directs the Gout, Hyperuricemia and Crystal-Associated Disease Network (G-CAN), a non-profit organization dedicated to creating research and education initiatives to fill the knowledge gap in gout.

“This Phase 4 study in gout is the first clinical trial launched by ANI as part of our commitment to building the scientific evidence and clinical data supporting the use of Cortrophin Gel,” said Mary Pao, MD, PhD, Chief Medical Officer of Rare Disease at ANI. “Our goal with the study is to generate meaningful clinical information for the dosing of Cortrophin Gel in patients with acute gout flares by comparing the safety and efficacy of two dose levels of the product. We believe this study will provide physicians with more data to inform their approach to patient care.”

“We have seen steady growth in the use of Cortrophin Gel as an adjunctive therapy for gout flares since we launched our 1-mL vial, which we developed to help increase access for in-office treatment, in October 2023,” said Nikhil Lalwani, President and Chief Executive Officer at ANI. “We believe our new Phase 4 study will provide valuable insights for patients and healthcare providers and further strengthen the profile of Cortrophin Gel in this indication.”

About the Cortrophin Gel Phase 4 Gout Trial
The Phase 4 trial is a randomized, single-center, double-blind, single administration study to evaluate the efficacy and safety of Cortrophin Gel at two dose levels (40 USP units/0.5 mL and 80 USP units/mL) administered as a single injection in patients with acute gout flares for whom non-steroidal anti-inflammatory drugs (NSAIDs) or colchicine did not previously provide an adequate response, among other criteria. The trial will randomize up to 160 patients in a 1:1 ratio between the two doses with the objective of enrolling 70 evaluable patients per dose group for the primary endpoint assessment.

Cortrophin Gel will be administered as a single dose, followed by a 7-day follow-up period with patient reported assessments conducted at days 1, 2, 3 and 7 post-administration. The primary endpoint of the study is the change in gout pain intensity from baseline in the target joint following Cortrophin Gel administration measured by Visual Analog Scale (VAS) at day 3 post-administration. Secondary endpoints include change in gout pain intensity at days 1, 2 and 7 post-administration, time to onset of effect, time to response, use of rescue medication, patient and physician assessments of response, and safety parameters. Exploratory endpoints include evaluating the effect of Cortrophin Gel on inflammatory biomarkers, health-related quality-of-life measures and health-care resource utilization.

Indication

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

- Short-term administration as an adjunctive therapy during an acute episode or exacerbation in acute gouty arthritis

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 reinstituted 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. 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 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, expedients, 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, including increased costs due to tariffs; 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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