ANI Pharmaceuticals Announces FDA Approval of Purified Cortrophin™ Gel for Multiple Indications Including Multiple Sclerosis, Rheumatoid Arthritis and Nephrotic Syndrome

November 1, 2021

-- Cortrophin Gel is purified corticotropin (ACTH), an important treatment option for patients struggling with certain chronic autoimmune disorders --

-- Approval re-introduces much needed patient and physician choice into the U.S. repository corticotropin market --

-- Early Q1 2022 full-scale launch planned --

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's supplemental New Drug Application (sNDA) for Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) (Cortrophin Gel) for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis (MS) and rheumatoid arthritis (RA), in addition to excess urinary protein due to nephrotic syndrome. Cortrophin Gel is an adrenocorticotropic hormone (ACTH), also known as purified corticotropin.

"FDA's approval of Cortrophin Gel enables us to bring a much-needed treatment choice to patients with acute exacerbations of multiple sclerosis and rheumatoid arthritis as well as nephrotic syndrome, who are coping with a devastating disease on a daily basis," said Nikhil Lalwani, President and Chief Executive Officer of ANI Pharmaceuticals. "We are pleased to offer Cortrophin Gel, an established treatment, to provide another option to patients and prescribers. This approval reflects ANI's commitment to the patients and physicians we serve, combined with U.S.-based development and manufacturing. We anticipate a full-scale commercial launch by early in the first quarter of 2022."

"Patients who are refractory or intolerant to corticosteroids have an especially urgent need for effective alternatives and are at risk of ongoing organ damage with long-term disease," said Mary Pao Seideman, MD, PhD, Chief Medical Officer of ANI Pharmaceuticals. "For over 30 years, there has only been one available treatment in the ACTH category. With the FDA approval of Cortrophin Gel, patients will now have a significant new treatment option."

Cortrophin Gel was first approved in 1954 and used for decades to treat certain chronic autoimmune disorders. ANI acquired the NDA for Cortrophin Gel from Merck & Co. in 2016. The Company has made a significant investment over the past five years in establishing and updating manufacturing processes and ensuring a sustainable, U.S.-based supply chain. ANI submitted an sNDA to the FDA in June 2021 to bring Cortrophin Gel back to market for patients, physicians and an overall healthcare system in need of greater access to ACTH therapies.

As part of its commitment to ensuring optimal access to Cortrophin Gel, ANI is investing in and will launch a patient support program including financial assistance such as copay cards, for eligible patients. Additional details on the program will be provided in conjunction with the commercial launch.

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; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; and suppression of growth in children. These are not all the adverse reactions reported with Cortrophin Gel.

Indications

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 rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis.
- Exacerbations or as maintenance therapy in select cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Severe erythema multiforme (Stevens-Johnson syndrome) and severe psoriasis.
- Atopic dermatitis and serum sickness.
- 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.
- Symptomatic sarcoidosis.
- Inducing a diuresis or remission of proteinuria due to nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Acute exacerbations of multiple sclerosis.

Please click here for full prescribing information for Cortrophin Gel.

About ANI Pharmaceuticals, Inc.
ANI Pharmaceuticals is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. For more information, please visit www.anipharmaceuticals.com.

Forward-Looking Statements
To the extent any statements made in this release relate to information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other words of similar meaning, derivations of such words, and the use of future dates. These forward-looking statements include statements regarding the commercial launch of Cortrophin Gel, the potential benefit of Cortrophin Gel to patients as a new treatment option, and expected timing of commercial launch and the size of the market opportunity for Cortrophin Gel. Risks and uncertainties that may cause the Company’s actual results to be materially different than those expressed in or implied by such forward-looking statements include, but are not limited to, the timing and costs involved in commercializing Cortrophin Gel, the ability to maintain regulatory approval of the product and maintain sufficiency of the product, the ability to obtain reimbursement from third-party payors for this product, the opinions and views of key opinion leaders and physicians who treat patients with chronic diseases and who may prescribe Cortrophin Gel, ANI’s ability to generate projected net product revenue and gain market share on the timeline expected, actions taken by competitors in response to a new market entrant, ANI’s reliance on third parties over which it may not always have full control, costs and regulatory requirements relating to contract manufacturing arrangements, increased competition and strategies employed by competitors, uncertainties regarding the COVID-19 pandemic, market trends for our products, regulatory environment and changes, and other risks and uncertainties that are described in ANI’s Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the U.S. Securities and Exchanges Commission.

Any 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. Except as required by law, 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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Source: ANI Pharmaceuticals, Inc.