

ACTON PHARMACEUTICALS, INC. SUBMITS NDA SUPPLEMENT TO FDA FOR AEROSPAN[®] (flunisolide HFA, 80 mcg) INHALATION AEROSOL

Preparations Underway to Launch Aerospan into the \$7 Billion Inhaled Steroid Market

MARLBOROUGH, Mass., Nov. 3, 2010 – Acton Pharmaceuticals, Inc. today announced that it has submitted to the U.S. Food and Drug Administration (FDA), a Manufacturing Supplement to the previously approved AEROSPAN Inhalation Aerosol NDA. Acton also announced that it has initiated commercial planning and market preparation activities for a product launch into the U.S. market targeted for mid-2011.

AEROSPAN is a hydrofluoroalkane (HFA) propelled inhaled corticosteroid for the treatment of asthma, which will compete in the \$7 billion U.S. inhaled steroid market¹. The AEROSPAN New Drug Application (NDA) has been approved by the FDA and the rights were acquired by Acton in 2009 under a licensing agreement with Forest Laboratories, Inc. (NYSE: FRX). Under the agreement, Acton assumed all marketing, sales and remaining manufacturing activities for AEROSPAN.

“We are very excited to achieve this important development milestone,” said Patrick A. Noland, Executive Vice President, Technical Operations. “By applying our expertise in chemistry, scientific method, and state of the art analytical techniques, we are providing a Manufacturing Supplement to establish procedures that should bring our product to full commercial scale. We hope to receive a response from the FDA around the end of the first quarter in 2011.”

AEROSPAN is the first HFA inhaled steroid to incorporate an integrated spacer device that assists patients in delivering their medication to the lung.

The company has initiated commercial scale up activities and plans to introduce AEROSPAN with its own specialty focused sales force. Acton is currently exploring co-promotion partnerships with primary care and pediatric focused pharmaceutical companies for the U.S. asthma market.

Clinical Trials

In a double-blind, parallel, placebo-and active-controlled clinical study of 669 adult and adolescent asthmatics aged 12-78 previously treated with inhaled corticosteroids, AEROSPAN Inhalation Aerosol was given for twelve weeks at doses of 80 mcg, 160 mcg or 320 mcg twice-daily (BID). Both approved doses, 160 mcg and 320 mcg, were significantly superior to placebo in the primary endpoint of FEV₁ (a test of lung function that measures the amount of air forcefully exhaled in one second). Secondary endpoints of AM peak expiratory flow rate, AM and PM asthma symptoms, nocturnal awakenings requiring a β 2 agonist, and as needed use of inhaled β 2 agonists showed differences from baseline favoring AEROSPAN over placebo.

Pediatric Patients with Asthma

AEROSPAN was studied in 583 asthma patients, 4 to 11 years of age, although the primary efficacy parameter, FEV₁, was evaluated only in the population of 513 patients 6 to 11 years of age. AEROSPAN Inhalation Aerosol was given at 80 mcg or 160 mcg BID. Results for the comparison versus placebo demonstrated a statistically significant improvement in change from baseline FEV₁ for the 80 mcg and 160 mcg doses of AEROSPAN, and there was no added benefit for the 160 mcg BID dose over the 80 mcg BID dose.

Important Safety Information

AEROSPAN Inhalation Aerosol is an orally inhaled corticosteroid indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age and older. AEROSPAN is not a bronchodilator and is not indicated for rapid relief of bronchospasm.

In clinical trials, AEROSPAN was generally well tolerated. Particular care is needed in patients transferred from systemically active corticosteroids to AEROSPAN Inhalation Aerosol because deaths due to adrenal insufficiency have occurred in asthmatic patients transferred from systemically active corticosteroids to less systemically active inhaled corticosteroids. The most common adverse reactions (>3%) were [headache](#), fever, allergic reaction, bacterial infection, pain and back pain, vomiting, dyspepsia, pharyngitis, rhinitis, cough, sinusitis, epistaxis, rash, and urinary tract infection.

Treatment with orally inhaled corticosteroids may lead to signs or symptoms of hypercorticism, suppression of hypothalamic-pituitary-adrenal (HPA) function and/or suppression of growth in children. [Glaucoma](#), increased intraocular pressure and [cataracts](#) have been reported following the administration of inhaled corticosteroids.

About Asthma

Asthma is a chronic disorder characterized by inflammation of the air passages, resulting in the temporary narrowing of the airways that transport air from the nose and mouth to the lungs. According to the National Heart Lung and Blood Institute (NHLBI), when taken every day, maintenance inhalers like AEROSPAN can help prevent the wheezing coughing, and tightening of the airways, which causes shortness of breath and can be life threatening. The NHLBI's Expert Panel Report estimates that more than 22 million Americans have asthma. Annually, the disease is responsible for nearly two million emergency room visits and accounts for an estimated \$11.5 billion in health care costs.

About Acton

Acton is a specialty respiratory pharmaceutical company dedicated to acquiring, developing, and commercializing prescription drugs to improve the well-being of patients. Acton's corporate headquarters are located in Marlborough, Massachusetts. To learn more about Acton, please visit our website at www.actonpharmaceuticals.com

¹ Source: IMS NPA

Aerospan is a registered trademark of Forest Laboratories, Inc.

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