



**ACTON PHARMACEUTICALS, INC. ANNOUNCES PUBLICATION OF AEROSPAN<sup>®</sup>  
(flunisolide HFA) PEDIATRIC LINEAR GROWTH STUDY IN *ANNALS OF ALLERGY,  
ASTHMA & IMMUNOLOGY***

**In This One Year Study, Flunisolide HFA Did Not Suppress Growth or Bone Maturation at the Highest  
Approved Dose for Children with Mild Persistent Asthma**

MARLBOROUGH, Mass., Oct. 11, 2011 – Acton Pharmaceuticals, Inc., a specialty respiratory pharmaceutical company, today announced that positive results from a Phase IIIB clinical trial of AEROSPAN were published this month in *Annals of Allergy, Asthma & Immunology* in a manuscript titled, “Linear growth and bone maturation are unaffected by 1 year of therapy with inhaled flunisolide hydrofluoroalkane in prepubescent children with mild persistent asthma: A randomized, double blind, placebo-controlled trial.” The abstract is available online at [http://www.annallergy.org/article/S1081-1206\(11\)00563-1/abstract](http://www.annallergy.org/article/S1081-1206(11)00563-1/abstract).

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.

In this double-blind, placebo-controlled study, 218 prepubescent children with mild persistent asthma were evaluated. After a two-week run-in period when no treatment was given, subjects were randomized to two puffs of flunisolide HFA twice daily (85 µg/puff) or placebo for 52 weeks. Height was assessed by stadiometry at each visit and growth velocity (cm/52 weeks) was estimated by the slope of the linear regression of height over time. In this study, there was no statistically significant difference between flunisolide HFA versus placebo in linear growth or bone maturation.

“Results from this trial will provide important information to physicians, particularly those who treat children with asthma,” said Kenneth Newman, M.D., Executive Vice President and Chief Medical Officer, Acton Pharmaceuticals, Inc. “It is not known whether these results would continue beyond one year and it is important for physicians to be alert for and to monitor growth in children due to the labeling precautions associated with inhaled steroids, including AEROSPAN.”

Inhaled corticosteroids (ICS) are the preferred long-term therapy for patients with persistent asthma. However, concerns remain about potential effects of long-term ICS use on growth in children. AEROSPAN is a HFA-propelled ICS and is the only approved HFA inhaler in its class to incorporate a built-in spacer device, which assists in the delivery of the medicine to the lungs. Acton licensed AEROSPAN from Forest Laboratories, Inc. (NYSE: FRX) and plans to commercialize AEROSPAN upon completion of certain manufacturing requirements. The value of the U.S. single-entity ICS market is approaching \$2 billion with more than 10 million prescriptions written per year.

**Important Safety Information**

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.

Treatment with orally inhaled corticosteroids including AEROSPAN, 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.

In clinical trials, AEROSPAN was generally well tolerated. 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.

### **About Asthma**

Asthma is a chronic disease of the lungs and airways characterized by wheezing, coughing, inflammation and a tightening of the airways, which causes shortness of breath and can be life-threatening. According to the National Heart, Lung and Blood Institute (NHLBI), when taken every day, maintenance inhalers like AEROSPAN can help prevent asthma symptoms. 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 developing prescription drugs to improve the well-being of patients. Acton's corporate headquarters are located in Marlborough, Massachusetts.

Aerospan is a registered trademark of Forest Laboratories, Inc.

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