



ACTON PHARMACEUTICALS, INC. ANNOUNCES LICENSE AGREEMENT WITH SANOFI U.S. FOR NASACORT HFA™ (triamcinolone acetonide) NASAL AEROSOL

Company's pipeline includes two NDA-stage respiratory compounds that will compete in the multi-billion dollar allergy and asthma steroid markets

MARLBOROUGH, Mass., October 25, 2011 – Acton Pharmaceuticals, Inc. (Acton), a specialty respiratory pharmaceutical company, announced today that it has completed a licensing agreement with Sanofi U.S. for prescription NASACORT HFA™ (triamcinolone acetonide) Nasal Aerosol for the treatment of nasal allergy symptoms. Under the agreement, Acton assumes the exclusive U.S. rights to develop and market NASACORT HFA in the \$2 billion prescription nasal steroid market.

NASACORT HFA is an intranasal steroid formulated with a hydrofluoroalkane (HFA) propellant and delivered as a fine, dry mist in a small volume pressurized metered dose. Currently, only aqueous (AQ) or water based liquid spray formulations of nasal steroids are available in the U.S. Under the agreement, Sanofi retains all rights to NASACORT® AQ.

“Acton’s research and development strategy is to apply our extensive chemistry experience to resolve manufacturing issues that often plague aerosol products during the FDA approval process,” stated Daniel Kreisler of Acton Pharmaceuticals. “The NASACORT HFA’s New Drug Application (NDA) was a FDA-approved aerosol product but was not commercially launched due to technical reasons related to manufacturing scale up. We believe that we can launch this important product into market. NASACORT HFA is another example of a commercial opportunity that targets a multi-billion dollar respiratory market.”

NASACORT HFA is in development as a once-a-day treatment for nasal symptoms associated with seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in adults and children 6 years of age and older. To date, Sanofi has conducted two Phase 3 studies of NASACORT HFA in clinical trials involving more than 1,100 patients. The most common adverse events reported in clinical studies (>3%) were sneezing, headache, nasal irritation and rhinitis.

In addition to NASACORT HFA, Acton is currently developing AEROSPAN® (flunisolide HFA) Inhalation Aerosol. AEROSPAN is a HFA-propelled aerosol inhaled corticosteroid (ICS) for the treatment of asthma. AEROSPAN is the first HFA inhaled steroid to incorporate a built-in spacer device, designed to assist patients in delivering their medication to the lungs. The NDA for AEROSPAN was FDA approved in 2006 and Acton licensed AEROSPAN from Forest Laboratories, Inc. (NYSE: FRX) in 2009 and plans to commercialize AEROSPAN upon completion of certain manufacturing requirements.

“The therapeutic indications of NASACORT HFA and AEROSPAN are complementary and will enable us to provide a highly targeted commercial effort directed toward respiratory and pediatric physicians,” stated John Simon of Acton Pharmaceuticals. “The size and scale of these markets combined with the peak sales potential of these products will enable us to further expand our reach among primary care physicians with a larger commercial partner.”

In clinical trials, AEROSPAN was generally well tolerated. In AEROSPAN’s clinical trials, the most common adverse events (>3%) were headache, fever, allergic reaction, bacterial infection, pain and back pain, vomiting, dyspepsia, pharyngitis, rhinitis, cough, sinusitis, epistaxis, rash, and urinary tract infection.

Combined, the inhaled and nasal steroid markets are valued at approximately \$9 billion in the U.S.

About NASACORT HFA

NASACORT HFA is an intranasal steroid formulated with a hydrofluoroalkane (HFA) propellant and delivered as a fine, dry mist in a small volume pressurized metered dose.

NASACORT HFA is being developed as a once-a-day treatment for nasal symptoms associated with seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in adults and children 6 years of age and older.

The clinical program of NASACORT HFA Nasal Aerosol included two Phase 3 studies conducted in the U.S. that involved 1,176 patients 12 to 83 years of age with allergic rhinitis, of which 729 patients were treated with NASACORT HFA Nasal Aerosol. One study was a two-week, double-blind, parallel-group, placebo-controlled trial comparing NASACORT HFA Nasal Aerosol to NASACORT Nasal Inhaler (triamcinolone acetonide CFC formulation) in 780 patients 18 years of age and older with seasonal allergic rhinitis

In the two-week, double-blind study, NASACORT HFA Nasal Aerosol and NASACORT Nasal Inhaler (triamcinolone acetonide CFC formulation) were comparable, and both formulations showed a statistically significant reduction in symptoms of allergic rhinitis. There were no significant differences in the effectiveness of NASACORT HFA Nasal Aerosol across subgroups of patients defined by gender, age, or race.

The second study was a 12-month open-label safety in 396 patients with perennial allergic rhinitis.

Adverse events occurring with an incidence of 3% or greater and more commonly with NASACORT HFA Nasal Aerosol arms compared to placebo irrespective of drug relationship include sneezing, headache, nasal irritation and rhinitis.

Safety Warnings

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency and, in addition, some patients may experience symptoms of withdrawal.

The concomitant use of intranasal corticosteroids with other inhaled corticosteroids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA axis.

About Allergic Rhinitis

Allergic rhinitis is a chronic inflammatory disease and includes a collection of symptoms predominantly in the nose and eyes, including sneezing, stuffy nose, and nasal itch. Seasonal allergic rhinitis (SAR) is sometimes referred to as hay fever, and is caused by an allergy to pollen.

Allergic rhinitis affects an estimated 50 million people in the U.S. and is the fifth leading chronic disease resulting in ~4 million missed or lost workdays each year and costing more than \$700 million in lost productivity.

Each year, nearly 17 million physician office visits are attributed to allergic rhinitis, with seasonal allergic rhinitis accounting for more than half of all allergy visits.

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. Nasacort[®], Nasacort[®] AQ, and Nasacort HFA[™] are trademarks of Sanofi.

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