Press Release

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GREER® Laboratories, Inc. Announces FDA Approval of ORALAIR®, the First Sublingual Allergy Immunotherapy Tablet, for the Treatment of Grass Pollen Allergy

ORALAIR® (Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass Mixed Pollens Allergen Extract) is the Only Sublingual Allergy Immunotherapy Tablet with a Mix of Five Grass Allergen Extracts

LENOIR, N.C. – April 1, 2014 – GREER® Laboratories, Inc., a leading developer and provider of allergy immunotherapy products and services, today announced that the U.S. Food and Drug Administration (FDA) has approved ORALAIR® (Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass Mixed Pollens Allergen Extract) sublingual allergy immunotherapy tablet. ORALAIR® is indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for grass pollen-specific IgE antibodies for any of the five grass species contained in the product. ORALAIR® is approved for use in persons 10 through 65 years of age.

Allergy immunotherapy in the United States has traditionally been administered via a series of subcutaneous injections in the allergy specialist's office. The approval of ORALAIR® provides an additional option for allergy specialists and patients to consider for treating grass allergies.

Grass allergies are the most common seasonal allergy in the United States[1,2] and most people are allergic to more than one type of grass.[3] ORALAIR® is the only FDA approved oral allergy immunotherapy tablet that includes a five grass, mixed pollens allergen extract. These five grasses provide a wide range of grass allergy coverage in the United States.

ORALAIR® is a tablet that dissolves under the tongue. The first dose is taken in the doctor's office under medical supervision, and subsequent doses are administered once a day by the patient or the patient's caregiver. ORALAIR® should be started four months before the expected onset of each grass pollen season and treatment continued throughout the season. ORALAIR® may reduce grass allergy symptoms for patients within the first allergy season that it is taken.

The ORALAIR® clinical program was based on safety, efficacy and tolerability results from an extensive set of clinical trials which included, in both the United States and Europe, over 2,500 adults and children. ORALAIR® was generally well tolerated and the most common adverse events (reported in ≥5% of patients) were oral pruritus, throat irritation, ear pruritus, mouth edema, tongue pruritus, cough, and oropharyngeal pain. Please see below for Important Safety Information, including content from the Boxed Warning.

GREER holds exclusive U.S. commercialization rights to ORALAIR® through its partnership with STALLERGENES, developer and manufacturer of the product.

“We are very pleased with the FDA’s approval of ORALAIR® and believe it will provide a valuable treatment alternative for many patients with grass allergies,” said John G. Roby, GREER president and CEO. “Until now there has not been a sublingual allergy immunotherapy tablet available for grass allergic patients. As part of our dedication to advancing allergy immunotherapy, we look forward to launching ORALAIR® with our partner STALLERGENES and bringing this treatment option to patients here in the U.S."

About ORALAIR®

ORALAIR® was originally approved in Europe in 2008 and is currently authorized in 31 countries around the world including most European countries, Canada, Australia, and Russia for the treatment of grass pollen allergy. In Canada, ORALAIR® was launched in 2012, making it the first allergy immunotherapy tablet to be registered and marketed in North America. World-wide post-marketing experience with ORALAIR® includes more than 20 million doses given to more than 110,000 patients.

ORALAIR® has been approved based on results from an extensive clinical development program. ORALAIR® has been studied in double-blind, placebo-controlled trials, in both Europe and the United States in over 2,500 adults and children. Positive results were achieved in these trials designed to demonstrate that pre-seasonal and co-seasonal treatment with grass allergy immunotherapy reduces patients’ allergy symptoms and their need for symptom-relieving medication.

Important Safety Information/Boxed Warning

ORALAIR® can cause life-threatening allergic reactions, such as anaphylaxis and severe laryngopharyngeal edema. ORALAIR® is contraindicated in patients with severe, unstable, or uncontrolled asthma or with a history of any severe systemic or local reaction to sublingual allergen immunotherapy. The first dose should be taken in a doctor’s office and the patient should be observed for at least 30 minutes. Patients should be prescribed auto-injectable epinephrine, trained on its appropriate use, and instructed to seek immediate medical care upon its use. Some medical conditions and medications may make patients unsuitable to take ORALAIR®. Please refer to the ORALAIR® full prescribing information for complete safety information, including the full text of the Boxed Warning.

About STALLERGENES

STALLERGENES is a global healthcare company specialized in the diagnosis and treatment of allergies. For more than 50 years, it has been continuously expanding the existing frontiers of science in order to provide allergy patients with more effective long lasting therapeutic options. Thanks to its innovation strategy, fueled by investments amounting to around 20% of total annual revenues as well as external cooperations, STALLERGENES is able to provide targeted allergen immunotherapy-based allergy solutions that significantly improve the lives of allergy patients around the world.

STALLERGENES operates in 20 countries and employs over 1,000 people. In 2013, the Company generated total revenues of €248 million, and more than 500,000 patients were treated with STALLERGENES products.

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Additional information is available at http://www.stallergenes.com

About GREER®

GREER® is a leading developer and provider of allergy immunotherapy products and services for treating humans and animals. As part of its commitment to allergy immunotherapy innovation, GREER's clinical development programs are focused on sublingual allergy immunotherapy liquid (SAIL)™. GREER will also market ORALAIR®, a sublingual allergy immunotherapy tablet with a mix of five grass allergen extracts, in the United States through its partnership with STALLERGENES. Sublingual immunotherapy is an extension of GREER's allergy immunotherapy products and provides another treatment option for allergy specialists to offer patients.

GREER was founded in 1904 and is located in Lenoir, North Carolina. For more information, visit www.greerlabs.com.

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[1] Salo PM, Calatroni A, Gergen PJ, et al. Allergy-related outcomes in relation to serum IgE: results from the National Health and Nutrition Examination Survey 2005-2006. *J Allergy Clin Immunol.* 2011;127(5):1226-1235.

[2] Arbes SJ Jr, Gergen PJ, Elliott L, Zeldin DC. Prevalences of positive skin test responses to 10 common allergens in the US population: results from the third National Health and Nutrition Examination Survey. *J Allergy Clin Immunol.* 2005;116(2):377-383.

[3] Esch RE. Grass pollen allergens. In: Lockey RF, Bukantz SC, eds. *Allergens and Allergen Immunotherapy*. 2nd ed. New York, NY: Marcel Dekker; 1999:103-120.