



## Press Release

Contact: Andrea Moody

Phone: 919-457-0743

Email: [andrea.moody@fleishman.com](mailto:andrea.moody@fleishman.com)

### **FDA Advisory Committee Supports Approval of ORALAIR<sup>®</sup> for the Treatment of Grass Pollen Allergy**

**LENOIR, N.C. – December 12, 2013** – [GREER<sup>®</sup> Laboratories, Inc.](#), a leading developer and provider of allergy immunotherapy products and services, today announced that the Allergenic Products Advisory Committee (APAC) of the U.S. Food and Drug Administration (FDA) voted that the available data support approval of the Biologic License Application (BLA) for ORALAIR<sup>®</sup> for the treatment of grass pollen-induced allergic rhinitis or conjunctivitis in adults and children confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species included in the product.

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

ORALAIR<sup>®</sup> is an investigational sublingual immunotherapy tablet that includes a five grass mixed pollens allergen extract from Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass. Grass allergies are the most common seasonal allergy in the United States and most people are allergic to more than one type of grass. The five grasses included in ORALAIR<sup>®</sup>, if approved, would provide a wide range of grass allergy coverage in the United States.

The FDA advisory committee supports the approval of ORALAIR<sup>®</sup> based on safety, efficacy and tolerability results from an extensive clinical development program which includes, in both the United States and Europe, over 2,500 adults and children. ORALAIR<sup>®</sup> was generally well tolerated and the most common treatment-emergent adverse events (greater than 10%) were application site reactions including oral pruritus and throat irritation. The FDA will likely consider the recommendations from the FDA advisory committee in its review of ORALAIR<sup>®</sup> but is not required to follow them.

“We are pleased with the Allergenic Products Advisory Committee’s positive vote for ORALAIR<sup>®</sup>,” said John G. Roby, GREER president and CEO. “Based upon this milestone, our goal is to continue to work with our partner STALLERGENES to bring ORALAIR<sup>®</sup> to patients in the United States as part of our dedication to advancing allergy immunotherapy.”

In October, GREER and STALLERGENES announced the signing of an exclusive agreement for the United States commercialization rights to ORALAIR<sup>®</sup>. Under the terms of the agreement, GREER would be responsible for the sales and marketing efforts for ORALAIR<sup>®</sup> in the United States and STALLERGENES would be responsible for the manufacturing and supply of the product.

### **About ORALAIR®**

ORALAIR® was originally approved in Europe in 2008 and is currently authorized in 29 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.

### **About STALLERGENES**

STALLERGENES is an international biopharmaceutical company dedicated to the treatment of allergy-related respiratory diseases, such as severe rhinoconjunctivitis and rhinitis, as well as allergic asthma, using allergy immunotherapy. The leader in sublingual immunotherapy treatments, STALLERGENES devotes around 20% of its annual gross revenues to Research & Development and is actively involved in the development of a new therapeutic class: sublingual immunotherapy tablets.

In 2012, the Company generated revenues of € 240 million, and more than 500,000 patients were treated with STALLERGENES products.

Euronext Paris (Compartment B)  
CAC small  
ISIN: FR0000065674  
Reuters: GEN.PA  
Bloomberg: GEN.FP



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 also plans to bring ORALAIR®, an investigational five-grass allergen immunotherapy tablet to the United States through its partnership with STALLERGENES. Sublingual immunotherapy would be an extension of GREER's allergy immunotherapy products and would provide 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](http://www.greerlabs.com).

MPN 121113H987