



# **Press Release**

# GREER<sup>®</sup> Laboratories, Inc. and STALLERGENES Sign Exclusive Agreement for United States Commercialization Rights to Oralair<sup>®</sup>

Oralair<sup>®</sup> is the only five-grass allergy immunotherapy tablet currently under review by FDA

**ANTONY, FRANCE and LENOIR, N.C. – October 31, 2013** – <u>STALLERGENES S.A.</u> (Euronext Paris), world leader in sublingual immunotherapy and <u>GREER<sup>®</sup> Laboratories, Inc.</u>, a leader in allergy immunotherapy in the United States today announced the signing of an exclusive agreement for the United States commercialization rights to Oralair<sup>®</sup>, an investigational grass allergy immunotherapy tablet currently under review by the FDA.

Oralair<sup>®</sup> is a grass pollen sublingual immunotherapy tablet that includes five grasses (sweet vernal grass, orchard grass, perennial rye grass, timothy grass, and Kentucky bluegrass) and is being investigated for the treatment of grass pollen-induced allergic rhinitis or conjunctivitis in adults and children aged 5 and older. 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 5 grasses included in Oralair<sup>®</sup> provide a wide range of grass allergy coverage in the United States. If approved, Oralair<sup>®</sup> would be a tablet that dissolves under the tongue and could be self-administered at home after receiving the first dose in a physician's office.

The application pending at FDA is based on results from an extensive clinical development program. Oralair<sup>®</sup> has been studied in double-blind, placebo-controlled trials, in both Europe and the United States in over 1,500 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. 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.

Under the terms of the agreement, GREER will lead the sales and marketing efforts for Oralair<sup>®</sup> in the United States and STALLERGENES will be responsible for tablet production and supply. STALLERGENES will receive regulatory and commercial milestone payments totalling up to \$120 million (USD), plus royalties and a transfer price.

"We believe that this partnership is an important first step, and if approved Oralair<sup>®</sup> will help to fill an unmet need for grass allergy sufferers who are candidates for allergy immunotherapy," said John G. Roby, GREER president and CEO. "Currently there are no FDA approved oral allergy immunotherapy treatments. GREER is committed to advancing allergy immunotherapy and we see this as a natural extension of our current R&D program for oral immunotherapy. We look forward to working with STALLERGENES to help bring this innovative product to both allergy specialists and patients here in the United States."

Roberto Gradnik, Chief Executive Officer of STALLERGENES said "We are delighted to team with GREER, a leader in allergy immunotherapy in the United States. GREER has in-depth knowledge of the United States allergy immunotherapy market and strong relationships with allergy specialists. This is the perfect combination, two complementary dedicated allergy immunotherapy companies working together to provide an innovative therapeutic solution for United States grass allergy sufferers."

# About Oralair<sup>®</sup>

Oralair<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>

GREER<sup>®</sup> 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)<sup>™</sup>. GREER also plans to bring Oralair<sup>®</sup>, an investigational fivegrass allergen immunotherapy tablet to the United States through its partnership with STALLERGENES. Sublingual immunotherapy will be an extension of GREER's allergy immunotherapy products and will 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 <u>www.greerlabs.com</u>.

#### Forward-looking statements related to Stallergenes

This press release may contain forward-looking statements, including forecasts of future revenue and operating profit as well as expected business-related events. Such statements are based upon the current beliefs and expectations of Stallergenes' management and are subject to risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements, due to various factors. Without being exhaustive, such factors include economic situations and business conditions, including legal and product evaluation issues, fluctuations in currencies and demand, changes in competitive factors and reliance on suppliers. The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information or future events and except as required by law.

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