

PRESS RELEASE

FDA ADVISORY COMMITTEE SUPPORTS APPROVAL OF STALLERGENES' ORALAIR® FOR THE TREATMENT OF GRASS POLLEN ALLERGY

Antony, France, 11 December 2013 – STALLERGENES S.A. (Euronext Paris), world leader in sublingual immunotherapy, 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 ORALAIR® for the treatment of grass pollen-induced allergic rhinitis or conjunctivitis in adults and children aged five and older.

ORALAIR® is a 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 grass pollens included in ORALAIR® represent those to which most patients in the U.S. are exposed.

The APAC supports approval of ORALAIR® based on safety, efficacy and tolerability results from an extensive clinical development program which includes trials in both the United States and Europe in over 2,500 adults and children. The recommendations of the APAC are not binding, but will be considered by FDA as the agency completes its review of the Biologics License Application (BLA).

Roberto Gradnik, Chief Executive Officer of STALLERGENES, said: "We are very pleased that the Advisory Committee has made a positive recommendation supporting the approval of ORALAIR® for the treatment of grass pollen-induced allergic rhinitis or conjunctivitis. We will continue to work with the FDA as it completes its assessment of the ORALAIR® BLA. We are convinced that ORALAIR®, the only five-grass allergy immunotherapy tablet to be potentially approved by FDA, will bring a true benefit to US patients suffering from grass pollen induced allergy."

In October, GREER and STALLERGENES announced the signing of an exclusive agreement for the United States commercialization rights to ORALAIR®. Under the terms of the agreement, GREER will lead the sales and marketing efforts for ORALAIR® in the United States and STALLERGENES will be responsible for tablet production and supply.

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 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 www.greerlabs.com.

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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