

# STALLERGENES GREER ANNOUNCES RESUMPTION OF MANUFACTURING AT ITS ANTONY, FRANCE PLANT

# DATE: February 1, 2016

London (United Kingdom) - Stallergenes Greer plc (the "Company") (Euronext Paris: STAGR), a biopharmaceutical company specializing in treatments for respiratory allergies, today announced that the manufacturing and distribution of ORALAIR®, ACTAIR® and ALYOSTAL® Venom¹ is starting after a temporary suspension at its Stallergenes SAS plant in Antony, France.

As previously communicated, this temporary suspension was enacted following observations made by the French Health Authority (ANSM), regarding the implementation of a new IT system aimed at providing upgraded supply and delivery of Stallergenes Greer's products. The launch of this new IT system resulted in operational disruptions that have now been satisfactorily addressed.

"We are pleased with the resumption of ORALAIR®, ACTAIR® and ALYOSTAL® Venom production. These products will be available again to our patients as soon as possible and in a sequential manner," said Fereydoun Firouz, Chairman and Chief Executive Officer of Stallergenes Greer.

Stallergenes Greer continues to work with the ANSM to promptly resume distribution of its Named Patient Products (NPP), including STALORAL<sup>®</sup>, PHOSTAL<sup>®</sup>, and ALUSTAL<sup>®</sup>.

# About ORALAIR®

ORALAIR® is a sublingual allergy immunotherapy tablet with a mix of five grass allergen extracts (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract).

ORALAIR® is a treatment for grass pollen allergic rhinitis with or without conjunctivitis in adults, adolescents, and children (above the age of five except in the United States, where it is approved for use in persons 10 through 65 years of age) with clinically relevant symptoms, confirmed by a positive cutaneous test and/or a positive titre of the specific IgE to the grass pollen. ORALAIR® is not indicated for the immediate relief of allergy symptoms.

ORALAIR® was originally approved in Europe in 2008 and is currently authorized in 31 countries around the world, including most European countries, United States, Canada, Australia, and Russia for the treatment of grass pollen allergic rhinitis. In United States, ORALAIR® was launched in May 2014, making it the first allergy immunotherapy tablet to be registered and marketed in United States. Worldwide post-marketing experience with ORALAIR® includes more than 20 million doses given to more than 110,000 patients.

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<sup>&</sup>lt;sup>1</sup> Allergy immunotherapy product indicated in the treatments of Hymenoptera venom allergies



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.

#### **Important Safety Information**

# WARNING: SEVERE ALLERGIC REACTIONS

ORALAIR® can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema. Do not administer ORALAIR to patients with severe, unstable or uncontrolled asthma. Observe patients in the office for at least 30 minutes following the initial dose. Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use. ORALAIR may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. ORALAIR may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

ORALAIR® is contraindicated in patients with severe, unstable or uncontrolled asthma, patients with a history of any severe systemic allergic reaction or severe local reaction to sublingual allergen immunotherapy, or patients who are hypersensitive to any of the inactive ingredients.

ORALAIR<sup>®</sup> can cause systemic allergic reactions, including anaphylaxis, and severe local reactions, including laryngopharyngeal swelling, which may be life-threatening. Severe and serious allergic reactions may require treatment with epinephrine. Patients who have a systemic allergic reaction to ORALAIR<sup>®</sup> should stop taking the product. Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue ORALAIR<sup>®</sup> in patients with persistent symptoms of eosinophilic esophagitis, including dysphagia or chest pain. ORALAIR<sup>®</sup> treatment should be withheld if the patient is experiencing an acute asthma exacerbation. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of ORALAIR<sup>®</sup>. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.

The most common adverse events reported in  $\geq 5\%$  of patients were oral pruritus, throat irritation, ear pruritus, mouth edema, tongue pruritus, cough, and oropharyngeal pain. Patients who have escalating or persistent local reactions to ORALAIR<sup>®</sup> should be reevaluated and considered for discontinuation of ORALAIR<sup>®</sup>.

Please see full Prescribing Information at:

http://www.oralair.com/assets/pdf/ORALAIR%20Prescribing%20Information-Med%20Guide.pdf including Medication Guide at http://www.oralair.com/assets/pdf/ORALAIR%20Med%20Guide.pdf

For jurisdictions information, please refer to the Oralair Summary of Product characteristics for the applicable jurisdiction. For more information on ORALAIR, visit www.oralair.com

# About ACTAIR® (STG320)

STG320 is a sublingual immunotherapy tablet consisting of Dermatophagoides pteronyssinus and Dermatophagoides farinae purified and calibrated House Dust Mites (HDM) extracts.

More than 2400 patients have been already enrolled in the STG320 allergic rhinitis program consisting of adults, adolescents, and children (at least 5 years of age) with allergic rhinitis caused by house dust mites, confirmed by positive skin tests and/or in vitro testing for dust mites-specific IgE antibodies.

The results of the natural field and environmental exposure chamber studies demonstrate that the 500 IR and 300 IR doses of STG320 have shown similar efficacy results in treating adults with HDM-induced allergic rhinitis. In the natural field study which followed patients post-treatment, efficacy was maintained over a treatment-free follow-up year. Efficacy analyses in adolescents have also shown a favorable effect with both doses. A favorable safety and tolerability profile was observed for all tested doses. There were no reports of anaphylactic shock, anaphylaxis, or Intensive Care Unit admission and no use of epinephrine. The most frequent adverse events were application site reactions such as oral pruritus and throat irritation. Most were of mild or moderate severity and were reported during the first weeks of treatment. Treatment-related adverse events leading to premature discontinuation were more frequent



with active treatment than placebo, and slightly more frequent with the 500 IR compared to 300 IR. The safety profile in children and adolescents was similar to that observed in adults. The review of the benefit-risk ratio of both doses led to the selection of the lowest dose 300IR

In March 2015, following completion of a randomized, double-blind, placebo controlled study evaluating the efficacy and safety of a 12 months treatment with STG320, the Japanese Pharmaceuticals and Medical Devices Agency approved ACTAIR® (STG320) as the first immunotherapy tablet for the treatment of HDM induced allergy in adolescents and adults.

Furthermore to the development plan, a phase III study to be conducted in adults and adolescents is in the recruiting phase in the US, Canada, Europe, Israel and Russia. The objective of this study is to confirm the efficacy and safety of the 300 IR dose of STG320 vs. placebo in adults and adolescents (12 to 65 years old). Approximately 900 patients are to be randomized 1:1 to receive daily a dose of 300 IR (with dose escalation) or placebo for 12 months.

#### ABOUT STALLERGENES GREER PLC

Headquartered in London (UK), Stallergenes Greer plc is a global healthcare company specializing in the diagnosis and treatment of allergies through the development and commercialization of allergy immunotherapy products and services. Stallergenes Greer plc is the parent company of GREER Laboratories, Inc. (whose registered office is in the U.S.) and Stallergenes S.A.S. (whose registered office is in France).

# **Trading information:**

Name: Stallergenes Greer

ISIN: GB00BZ21RF93 1 - Ticker: STAGR

ICB classification 4577

Market: Euronext Paris regulated market

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

This document (including information incorporated by reference in this document), oral statements made and other information published by the company contain statements that are or may be forward-looking with respect to the financial condition and/or results of operations and businesses of the Company. These statements can be identified by the use of forward-looking terminology such as "believe", "expects", "project", "estimated", "forecast", "should", "plan", "may" or the negative of any of these, or other variations thereof, or comparable terminology indicating expectations or beliefs concerning future events. These forward-looking statements include risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. Without being exhaustive, such factors include economic situations and business conditions, including legal and product evaluation issues, fluctuations in currencies and demand, and changes in competitive factors. These and other factors are more fully described in our prospectus filed with the French Autorité des marchés financiers on September 3, 2015. Actual results may differ from those set forth in the forward-looking statements, due to various factors. Save as required by applicable law, neither the Company nor any other person assumes any obligation to update these forward-looking statements or to notify any person of any such update.



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