PRESS RELEASE

STALLERGENES ANNOUNCES FDA APPROVAL OF ORALAIR®, THE FIRST SUBLINGUAL IMMUNOTHERAPY TABLET FOR THE TREATMENT OF GRASS POLLEN ALLERGY

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

Antony (France), 1 April 2014 – STALLERGENES S.A. (Euronext Paris), the world leader in sublingual immunotherapy, today announced that the U.S. Food and Drug Administration (FDA) has approved ORALAIR®, the first immunotherapy tablet to be available in the U.S. for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis.

Until now, allergen immunotherapy has been administered via a series of subcutaneous injections in the allergy specialist's office. The approval of ORALAIR provides an additional treatment option for allergy specialists and their patients.

Grass allergy is the most common seasonal allergy in the United States and most people are allergic to more than one type of grass. ORALAIR contains a mix of five grass pollens: Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass. The five grass pollens contained in ORALAIR represent those to which most patients in the U.S. are exposed.

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 pollen-specific IgE antibodies for any of the five grass species contained in this product. ORALAIR is approved for use in persons 10 through 65 years of age.

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 treatment should be started four months before the expected onset of each grass pollen season and continued throughout the season. Allergy symptoms are reduced beginning with the first grass pollen season.

"We are very pleased with the U.S. approval of ORALAIR as it will bring a true benefit to US patients suffering from grass pollen-induced allergy", said Christian Chavy, newly appointed Chief Executive Officer of STALLERGENES. "This approval is a major milestone for Stallergenes. The company not only developed ORALAIR but it also continues to expand the frontiers of allergen immunotherapy. I would like to congratulate my predecessor, Roberto GRADNIK and his teams on this major achievement."

He added: “We look forward to launching ORALAIR with our partner, GREER®, a leader in the U.S. allergen immunotherapy market with strong and long-standing relationships with allergy specialists. Thanks to ORALAIR, U.S. allergy specialists will now be able to offer a valuable treatment alternative to their patients with grass pollen-induced allergy, including those likely to refuse or prematurely discontinue subcutaneous immunotherapy.”

In October 2013, GREER® and STALLERGENES announced the signing of an exclusive agreement for the U.S. 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. The approval of ORALAIR triggers a milestone payment from GREER® to STALLERGENES of $10 million (USD), which amount will be capitalized and recognized as revenue over the life of such agreement. Overall, under such agreement STALLERGENES would receive payments on the occurrence of regulatory and commercial milestone events totalling up to $120 million (USD), plus royalties and a transfer price.

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. Worldwide 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. The results of these trials demonstrated that pre-seasonal and co-seasonal treatment reduces patients’ allergy symptoms and their need for symptom-relieving medication. In the clinical development program, the most common adverse reactions for ORALAIR (reported in ≥5% of patients) were oral pruritus, throat irritation, ear pruritus, mouth edema, tongue pruritus, cough, and oropharyngeal pain.

ABOUT THE U.S. ALLERGEN IMMUNOTHERAPY MARKET

The U.S. market offers substantial potential for the development of sublingual immunotherapy: allergic rhinitis affects 60 million people and the most prevalent allergen is grass pollen. Each year, 12.5 million people consult a physician for symptoms of grass pollen allergy.

Today, fewer than 3 million allergy sufferers (i.e., 5% of the U.S. allergic population), are treated with allergen immunotherapy. The current standard of care for immunotherapy is multiple injections administered in a supervised medical setting. There is a strong need for an innovative sublingual treatment that enables patient self-administration.

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.

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 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.

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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