# STALLERGENES

# PRESS RELEASE

### POSITIVE RESULTS FROM A PHASE IIb/III CLINICAL TRIAL ON THE HOUSE DUST MITE DESENSITIZATION TABLET

Antony, France (April 29, 2009) Stallergenes S.A. announces the release of the first year outcome of its phase IIb/III clinical trial (VO 57.07) on a sublingual house dust mite desensitization tablet.

"We are very pleased with the outcome of this study, which is the first large study to ever demonstrate the efficacy of house dust mites allergen in treating perennial allergic rhinitis. Furthermore, the unexpected quick onset of action and the good safety profile are addressing the needs of patients with moderate to severe forms of the disease. This study will be pivotal in the European registration process of our house dust mites sublingual tablet, and the basis for further developments in our program" states Albert Saporta, Chairman and CEO of Stallergenes. "This study is a genuine landmark which confirms desensitization as a new therapeutic class in the management of allergic respiratory disorders. Stallergenes has been consolidating its leadership in this field through its innovative and development capabilities".

Stallergenes has been conducting a phase IIb/III clinical trial, with a sublingual tablet in adults suffering from moderate to severe persistent allergic rhinitis to house dust mites, including 509 patients, over seven countries, with a full year of treatment from January to December 2008. This study compared two treated groups, one with a daily intake of 300 IR<sup>1</sup> sublingual tablet, the other of 500 IR, with a placebo group. The endpoint was the adjusted average symptom score on nasal symptoms assessed during the three last months of the year.

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The two treated groups have demonstrated a highly significant statistical difference on the primary endpoint versus the placebo group ( $p \le 0.0136$ ), with no difference between the two treated groups. In the different groups, use of rescue medication was allowed throughout the period. The adjusted average symptom score has been improved by 20% in both treated groups. In particular, the nasal congestion score has been improved by 40% (median) and the nasal pruritus by 32% (median). The safety profile has been highly satisfactory.

<sup>&</sup>lt;sup>1</sup> \* Index of Reactivity for standardized extracts

For the same level of efficacy, the 300 IR tablet has been selected.

Furthermore, the onset of action was achieved from the 4<sup>th</sup> month of treatment, meaning that the difference between the placebo and the treated groups was statistically significant, the treatment effect being maintained at the same level up to the end of the study.

The quality of life has been statistically improved and the proportion of symptomcontrolled days increased by 52%.

The study will be pursued over 1 year on an observational basis in accordance with protocol.

"The conduct of clinical trials in perennial allergic rhinitis is a major challenge. The outcomes of the VO57.07 are clearly good and consistent, clinically important and relevant", said Prof. Karl-Christian Bergmann, international coordinator of the study. "These results are more than promising for the roll-over of the development of house dust mites sublingual desensitization therapy".

## ABOUT HOUSE DUST MITES ALLERGIC RHINITIS

In Europe, on average, almost 40% of respiratory allergic conditions are caused by house dust mites, making this the leading cause of respiratory allergy ahead of grass pollens. From early childhood, house dust mites can trigger allergic rhinitis, worsening over time with a natural progression towards asthma. The symptoms may be severe, significantly impairing patients' quality of life.

# ABOUT THE STALAIR® DEVELOPMENT PROGRAM

According to World Health Organization (WHO) estimates, 20 to 25% of the world's population currently suffers from respiratory allergic symptoms (rhinoconjunctivitis, rhinitis and/or asthma). By 2020, 50% of the world's population may be affected by at least one allergy according to the ISAAC study. For nearly 15 to 20% of patients currently suffering from severe allergic rhinitis and rhinoconjunctivitis, their condition is not adequately controlled and has an adverse effect on their quality of life.

Sublingual desensitization therapy is fully recognized and coded by international consensus (ARIA), under the aegis of WHO. Supported by a high level of evidence, this consensus recommends the use of desensitization therapy when the patient's allergy is not adequately controlled by symptomatic treatments, which act on the symptoms of the condition without addressing its cause.

To date, desensitization therapy is the only treatment option that treats the immunological causes of allergies and modifies the natural course of the disease, preventing it from worsening.

Since 2003, Stallergenes has been running the Stalair® program, which aims to address the immunological cause of respiratory allergies with EBM-documented, registered allergen tablets. This program consists in the development of tablets for five of the main allergens triggering more than 80% of allergies: grass pollens, house dust mites, birch pollen, ragweed pollen, Japanese cedar pollen. The

entire program is in the clinical development stage and is proceeding according to schedule.

The first tablet from the program, Oralair<sup>®</sup> (a desensitization tablet for grass pollens) is available in Germany for adults and children. This tablet is currently being evaluated in other European countries, with a view to bringing it to market in 2010.

#### **ABOUT STALLERGENES**

Stallergenes is a European biopharmaceutical company dedicated to desensitization therapies for the prevention and treatment of allergy-related respiratory diseases, such as rhinoconjunctivitis, rhinitis and allergic asthma. A pioneer and leader in sublingual desensitization treatments, Stallergenes devotes 21% of its turnover, in gross terms, to Research and Development and is actively involved in the development of a new therapeutic class: sublingual desensitization tablets.

In 2008, Stallergenes had a turnover of 171 million euros and more than 500,000 patients were treated with Stallergenes desensitization products.

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

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