

**PRESS
RELEASE****ORALAIR® GRASSES 300IR
HIGHLY POSITIVE CLINICAL RESULTS IN A PHARMACODYNAMIC
STUDY CONDUCTED IN AN ALLERGEN CHALLENGE CHAMBER**

Antony, France; August 27th, 2008 – Stallergenes S.A. announces the highly positive results of a new study conducted in an Allergen Challenge Chamber (ACC).

The study on Oralair® Grasses included 86 adult patients exposed to grass pollen challenge with different treatment durations: 1 week, 1 month, 2 and 4 months without a titration phase. Use of rescue medication was not allowed.

The outcomes of this trial in line with the objectives were:

- An onset of action starting on the seventh day (statistically significant at one month)
- An efficacy plateau reached on challenge at the first month
- A highly statistically significant effect of Oralair® Grasses versus placebo ($p=0.0003$) on the average symptom score (RTSS). The magnitude of efficacy (34%)¹ was similar to the findings of the previous studies VO34 (in adults) and VO52 (in a paediatric population)
- A Cohen score of 0.79 corresponding to a large effect size

Safety results, with only well-known local adverse events, and efficacy results were consistent with the findings of Oralair® Grasses studies previously conducted in adults (VO34) and children (VO52) in phase III trials.

“This study has demonstrated a clear consistency with the outcomes of previous pivotal studies. It opens the way for ACC as a new tool for phase II studies reducing the unpredictability of pollination. Moreover, it confirms the therapeutic effect of Oralair® Grasses and the very fast onset of action on the symptoms,” said Olivier de Beaumont.

¹ on median scores

ABOUT THE STUDY

This was a randomised, double-blind, parallel-group, placebo-controlled, single centre, phase I study to assess, subsequent to allergen challenge in an allergen exposition chamber, the efficacy and time course of sublingual immunotherapy (SLIT) administered as 300IR allergen-based tablets once daily to 86 adults suffering from grass pollen rhinoconjunctivitis. The main objectives of the study were to assess the efficacy of grass pollen extract SLIT tablets compared to placebo on the average Rhinoconjunctivitis Total Symptom Score (sneezing, rhinorrhea, nasal pruritus, nasal congestion, ocular pruritus and watery eyes), to evaluate the onset of action after different treatment durations (1 week, 1 month, 2 and 4 months) through the challenge test, to identify immunological parameters as possible biomarkers for SLIT, and to assess safety. Since patients were not allowed to take any rescue medication, the symptom score was not impacted by its usage and the difference between the placebo and active group was due exclusively to the effect of the Oralair[®] Grasses tablet.

ABOUT THE ALLERGEN CHALLENGE CHAMBER (ACC)

The Allergen Challenge Chamber is already recognized as a supportive study by the FDA and the European Medicines Agency (EMA). The interest of ACC as an assessment tool for clinical development is confirmed. The Allergen Challenge Chamber (ACC) offsets the unpredictability of the pollen season, and thereby avoids the variable nature of pollens and patient exposure and facilitates follow up.

ABOUT ORALAIR[®] GRASSES

Oralair[®] Grasses is a fast-dissolving tablet that has demonstrated high efficacy in treating allergic rhinoconjunctivitis to grass pollen starting with the first season, lasting throughout the pollen season, and at the pollen peak, on:

- Poly- and mono-sensitised patients, as well as asthmatic patients,
- Every individual symptom, and in particular on nasal congestion and watery eyes.

Oralair[®] Grasses is a pre-seasonal treatment: it has to be started four months before the pollen season, be maintained throughout the season, and then stopped and restarted the following season.

Oralair[®] Grasses contains a mix of 5 standardised grass allergens: perennial rye grass (*Lolium perenne*), meadow grass (*Poa pratensis*), timothy grass (*Phleum pratense*), cocksfoot (*Dactylis glomerata*) and sweet vernal grass (*Anthoxanthum odoratum*), as a daily dose of 300 IR, so as to mimic patients' natural exposure.

In June 2008, Stallergenes was granted a marketing authorisation for Oralair[®] Grasses in adults, by PEI (Paul Ehrlich Institute), the biological branch of the German health agency.

Based on the positive results of the paediatric pivotal study (VO52), Stallergenes has applied in July 2008 for the paediatric extension of the product's indications.

The clinical development programme has already enrolled around 1600 patients to date. A long term pivotal study is proceeding according to schedule, and is currently in its second year. The company plans to file two INDs for adult and paediatric trials with the FDA this year.

ABOUT STALLERGENES

Stallergenes is a European biopharmaceutical company dedicated to desensitisation therapies for the prevention and treatment of allergy-related respiratory diseases, e.g. rhinoconjunctivitis and allergic asthma. A pioneer and leader in sublingual desensitisation treatments, Stallergenes devotes 16% of its turnover to Research and Development and is actively involved in the development of a new therapeutic class: sublingual desensitisation tablets.

In 2007, Stallergenes had a turnover of 147 million euros and provided desensitisation treatments to more than 500,000 patients.

Stallergenes is listed on Euronext Paris (Compartment B) and is part of the sample composing the SBF 120 index.

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