STALLERGENES

PRESS RELEASE

VERY POSITIVE 3-YEAR RESULTS OF THE LONG-TERM STUDY PROVIDE CONFIRMATION OF THE CLINICAL RELEVANCE OF ORALAIR®

Antony, France (December 7, 2009). Stallergenes S.A. today announces the 3-year results of a phase III clinical trial (VO53.06) to assess the long-term (sustained) effect and disease modifier effect after discontinuation of treatment of its sublingual grass pollen immunotherapy tablet, Oralair®. This study is the first ever pivotal study designed to be a long-term and disease modifier trial from the outset.

The VO53.06 study is a randomized, double-blind, placebo-controlled phase III trial conducted over 5 years, 3 years as a pre- and coseasonal treatment regimen and the following 2 years without treatment. It included 633 patients, aged 18 to 50 years, with grass pollen-related allergic rhino-conjunctivitis, in 45 centers in 10 countries. The patients were divided in two treated groups and one placebo group. In the two active arms, there was no dose escalation and the daily dose was a 300 IR sublingual immunotherapy tablet. In one active arm, the treatment started 4 months before the pollen season, and in the other, 2 months before. The total treatment duration for each study-year in all groups was 5 to 6 months up until the end of the pollen season.

The sustained clinical efficacy as defined by EMEA[1] guidelines is the measurement of treatment efficacy after 3 years. The primary endpoint was the Average Adjusted Symptom Score (AASS)[2].

In the third year analysis, the two treated groups demonstrated a statistically significant reduction of AASS in comparison with placebo ($p<0.0001$) with a very large effect.

Relative differences versus placebo (season 3)

	2 months	4 months
Mean	-36%	-34%
Median	-50%	-48%

A reduction of 40% was achieved in the 2nd year and a reduction of 30% in the 1st year (relative median differences versus placebo). These results not only demonstrate the sustained clinical effect of Oralair® administered using a pre- and coseasonal treatment regimen but also suggest an increase in efficacy over the seasons.

In addition, each of the six individual symptom scores has demonstrated a statistically significant improvement. All the outcomes obtained in the secondary endpoints were statistically significant and consistent with those of the primary endpoint.

---

[1] European Medicines Agency

[2] AASS: Average Adjusted Symptom Score: A score taking into account the daily rhino-conjunctivitis total symptoms score and rescue medication usage.

Patient compliance was very satisfactory over the three seasons and the overall tolerance was excellent.

In accordance with the recommendation of a board of independent experts (Data and Safety Monitoring Board), the study will be continued over the next 2 years in order to assess the disease modifier effect (maintenance of therapeutic benefit after treatment discontinuation).

In addition to this long-term study, in 2009 Stallergenes conducted a phase III one-season optimization study (VO60.08) with Oralair® 300 IR. This randomized, double-blind, placebo-controlled study was performed without dose escalation and used a 2-month pre-seasonal treatment regimen. In this trial, 180 patients were enrolled in each of the two arms. The analysis on the primary endpoint did not reach a statistically significant difference, although positive trends were demonstrated. Further in-depth analyses will be performed, to identify likely methodological bias.

"We are very enthusiastic about the results of the VO53.06 study which far exceed our expectations. We will file for an extension of the product's current labeling, as defined in the marketing authorization recently obtained via a Mutual Recognition Procedure (MRP) in 23 European countries. Such setbacks due to the VO60.08 study outcome can occur in any large development program, and in no way call into doubt the overall findings of the Oralair® program as a whole, which remain extremely consistent. The development program, which focuses on the benefit to patients and fits squarely with current cost-containment trends, confirms the relevance of Stallergenes' strategic choices.
Our 2009 clinical news flow has been very dense and is not over yet. There are still more results to come and more analyses to be conducted. We will be delighted to present all these findings at an R&D day to be held at the start of 2010." says Albert Saporta, Chairman and CEO of Stallergenes.

ABOUT ORALAIR®

The Oralair® clinical development program has demonstrated the short-term efficacy of the product at an appropriate dose of 300 IR during the first season, through two clinical studies in adults and children (VO34.04 and VO52.06).

Through a pharmacodynamics study (V056.07), Stallergenes demonstrated that its immunotherapy tablet had an effect on symptoms from the very first month of treatment, without the use of rescue medication and irrespective of variable patient exposure to pollen.

The Oralair® development program, which has so far included over 1,800 patients, makes the level of clinical evidence for this treatment indisputable. This program, which was initiated in 2003 and is fully in line with EMEA guidelines issued in 2008, will help immunotherapy tablets achieve the same level of recognition as conventional pharmaceuticals.

From the outset, the Oralair® clinical development program has addressed the key issues involved in grass pollen immunotherapy:

- It answers the unmet needs of patients suffering from severe rhino-conjunctivitis caused by grass pollen, inadequately controlled using symptomatic treatments,
- It favors compliance and cost-containment, through its pre- and coseasonal protocol (the treatment is taken for four months prior to the pollen season and then throughout it, for three consecutive seasons) rather than a perennial protocol (when the treatment is taken all year round),

- Its active substance consisting of a set of five pollens corresponds to the epidemiological characteristics of patient exposure in Europe.

ABOUT THE STALAIR® PROGRAM

Stalair® is the pharmaceutical and clinical development program for immunotherapy tablets being implemented by Stallergenes with a view to obtaining marketing registrations for pharmaceutical products in Europe and in other strategic markets.

Oralair® is the first project resulting from this program. A Mutual Recognition Procedure has been completed. The results of a phase III clinical study conducted in adults in the USA are expected in the coming weeks.

A positive phase IIb/III study was completed for the dust mite immunotherapy tablet, Actair® in allergic rhinitis in adults during the first half of 2009. A pediatric phase III study has been launched.

The Bet v 1 tablet (birch pollen recombinant) has been the subject of a positive phase IIb/III clinical trial conducted in allergic rhinitis caused by birch pollen. A confirmatory phase III study is currently being prepared with a view to EMEA registration.

The other allergens concerned by the program are ragweed for the North American market and Japanese cedar pollen for the Japanese market. Altogether, the program covers 80% of the epidemiology for all markets.

ABOUT STALLERGENES

Stallergenes is a European biopharmaceutical company dedicated to immunotherapy treatments for the prevention and treatment of allergy-related respiratory diseases, such as allergic rhinoconjunctivitis, rhinitis and asthma. As of today, Stallergenes is the seventh-ranked French pharmaceutical company. A pioneer and leader in sublingual immunotherapy 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 immunotherapy tablets.
In 2008, Stallergenes had a turnover of 171 million euros and more than 500,000 patients were treated with Stallergenes immunotherapy products.

Euronext Paris (Compartment B)
SBF 120.

ISIN code: FR0000065674
Reuters code: GEN.PA
Bloomberg code: GEN.FP

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

Contacts
Albert Saporta – Chairman and CEO
Tel.: +33 1 55 59 20 04

Christian Thiry – Financial Director
Tel.: +33 1 55 59 20 95
e-mail: investorrelations@stallergenes.fr

Press relations
Lise Lemonnier – Communication Manager
Tel.: + 33 1 55 59 20 96
e-mail: llemonnier@stallergenes.fr

Investor and analyst relations
Lucile de Fraguier – Pavie Finance
Tel.: + 33 1 42 15 04 39
e-mail: contact@pavie-finance.com