

STALLERGENES

PRESS RELEASE

PERSISTENT EFFICACY DEMONSTRATED AFTER A YEAR ON ACTAIR® FOLLOWED BY A SECOND TREATMENT-FREE YEAR

Antony, France (June 28, 2010) – After having announced positive results for the first year of its phase IIb/III clinical trial (VO 57.07) conducted on Actair® sublingual allergen immunotherapy tablets in allergic rhinitis triggered by house dust mites in April 2009, Stallergenes S.A. today announces the results of the second year of this study.

Following this first year which demonstrated positive results for both the dosages tested (300 IR¹ and 500 IR) and which is key for the marketing authorization application, the second year of the study involved an exploratory evaluation of the persistence of the therapeutic effect of Actair® in the following year. Out of the 509 patients originally included in the study, 397 participated until the end of the second year. The primary endpoint for this second year was the Average Adjusted Symptom Score (AAdSS)² measured one year after the end of treatment.

The results of this second year demonstrate not only that the efficacy of Actair® persists well beyond the first six months after treatment is stopped but also that the size effect is globally equivalent to that observed in the first year. Thus in the main assessment period for the efficacy endpoint (between 10 and 12 months after the discontinuation of treatment), both active groups demonstrated a persistent effect of the treatment, with a statistically significant difference for the AAdSS versus placebo [(p=0.0342) for the 300 IR dosage; (p=0.0229) for the 500 IR dosage], still with no difference between the two treated groups.

This study is a world first in that, for the first time, it indisputably demonstrates the persistence of the effect of sublingual allergen immunotherapy in perennial allergic rhinitis triggered by house dust mites, as well as the early onset of this effect, from the end of the first year. The duration and the dynamics of this effect will have to be explored.

“We’re clearly delighted with these results. For the first time ever, the persistence of the therapeutic effect of allergen immunotherapy has been demonstrated after only a year. This is yet another illustration of the contribution that the large-scale studies conducted as part of the Stalair® clinical development program can make to our understanding of allergen immunotherapy”, says Albert Saporta, Chairman and CEO of Stallergenes. “Like the trial conducted in asthma triggered by house dust mites with Staloral® 300 in China, this study will help us construct a development plan for Actair® that is ambitious in terms of the indications

¹ Reactivity index for standardized extracts

² AAdSS: Average Adjusted Symptom Score taking into account the total daily rhinoconjunctivitis symptom score and recourse to authorized rescue treatments.

envisaged and realistic, proposing discontinuous protocols that meet the expectations of both patients and health system paying authorities.”

ABOUT ALLERGIC RHINITIS TRIGGERED BY HOUSE DUST MITES

In Europe, almost 40% of allergic respiratory diseases, on average, are triggered by house dust mites, making this the leading cause of respiratory allergy, ahead of grass pollens. Dust mites are responsible for allergic rhinitis that begins in early childhood, gradually worsens over time and naturally progresses to asthma. These conditions have marked symptoms that significantly impair patients' quality of life.

ABOUT STALAIR®

Stalair® is the name of the pharmaceutical and clinical development program for immunotherapy tablets being implemented by Stallergenes with a view to obtaining market authorizations 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 in Europe. Having recently demonstrated its efficacy after 3 years of treatment (study VO53.06 conducted in Europe), Oralair® has been the subject of a positive phase III trial in adults in the United States (VO61.08).

The second project in the program is Actair®, dust mite immunotherapy tablet. Following the results of the first year of the phase IIb/III study in allergic rhinitis in adults, a phase III pediatric study has been launched.

The Stalair® r Bet v 1 tablet (birch pollen recombinant allergen) 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 EMA registration.

The other allergens concerned by the program are ragweed pollen 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 STALORAL® 300

Staloral® 300 is a sublingual solution of allergen extracts for allergen immunotherapy. It is indicated in the treatment of allergic rhinitis, rhinoconjunctivitis and seasonal or perennial mild to moderate allergic asthma in adults and children over the age of 5 years. Prescribed by allergy specialists, Staloral® 300 is particularly aimed at patients suffering from severe allergic diseases inadequately controlled by the use of symptomatic treatments.

In the context of a phase III clinical trial (VO55.06) conducted in China, Staloral® 300 has demonstrated its efficacy in the control of asthma triggered by house dust mites on the basis of “well-controlled asthma” and “total asthma control” criteria in adult GINA 3 patients (moderate asthma stabilized by inhaled corticosteroids).

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. Stallergenes is the seventh-ranked French pharmaceutical company. A pioneer and leader in sublingual immunotherapy treatments, Stallergenes devotes more than 20% 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 2009, Stallergenes had a turnover of 193 million euros and more than 500,000 patients were treated with Stallergenes immunotherapy products.

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