

# STALLERGENES PRESS RELEASE

## POSITIVE RESULTS FOR ORALAIR® PHASE III TRIAL IN THE USA

**Antony, France (April 19, 2010).** Stallergenes S.A. today announced the first results of a phase III clinical trial (VO61.08) conducted in the USA on its sublingual grass pollen immunotherapy tablet, Oralair®.

This phase III study is the first clinical study in the USA to be conducted by Stallergenes as part of the Oralair® clinical development which already encompassed 4 phase III clinical trials conducted in Europe. This development program has so far included over 2,300 patients. This study is pivotal in the perspective of a market authorization application for Oralair® in the USA with an adult indication (BLA<sup>1</sup>).

The VO61.08 study is a randomized, double-blind, placebo-controlled, phase III trial. It included 473 adult patients, aged 18 to 65 years, suffering from grass pollen-induced rhinoconjunctivitis, in 51 centers in the United States. The patients were divided into two arms: one group was treated with Oralair® and the other with a placebo. The primary endpoint was the reduction of the "combined score", taking into account symptoms and rescue drugs.

The study achieved its objective on the primary endpoint: the reduction of the combined score obtained by Oralair® compared to the placebo is statistically very significant and of a similar magnitude to the results of European studies. The product was very well tolerated.

"We are proud to have conducted this study in the USA and very satisfied with the results obtained which confirm the high level of evidence in support of Oralair®" commented Albert Saporta, Chairman and CEO of Stallergenes. "We have passed an important milestone in our strategy for the US market and are actively preparing the registration file with a view to filing a Market Authorization application in early 2011."

### ABOUT ORALAIR®

The Oralair® active substance consists of five purified and calibrated pollen extracts corresponding to the epidemiological characteristics of patient exposure in Europe: perennial rye grass (*Lolium perenne*), meadow grass (*Poa pratensis*), timothy grass (*Phleum pratense*), cocksfoot (*Dactylis glomerata*) and sweet vernal grass (*Anthoxanthum odoratum*).

From the outset, its clinical development has taken into account the benefit to patients: proven efficacy, safety, ease of use, compliance, and cost-containment through a 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.

The clinical development program for Oralair® is continuing. Stallergenes has recently announced the positive 3-year results of a phase III clinical trial (VO53.06) intended to assess the long-term or sustained effect of Oralair® along with maintenance of the therapeutic benefit after treatment discontinuation (disease-modifier effect). This study is the first ever pivotal study designed to

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<sup>1</sup> BLA: Biologics License Application

measure this dual effect from the outset. It will continue for 2 years without treatment so that the disease-modifier effect can be fully assessed.

## **ABOUT THE STALAIR® PROGRAM**

Stalair® is 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.

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

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

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