

PRESS RELEASE

STALLERGENES BECOMES WORLD'S LEADING PRODUCER OF GRASS POLLENS AND HOUSE DUST MITES

Antony, France (20 January 2011) Stallergenes S.A. announces the opening of its new raw materials production unit in Amilly, le Loiret (France).

This production facility is currently dedicated to the collection and processing of grass pollens used for the manufacture of allergen immunotherapy treatments and, most notably, the grass pollen sublingual immunotherapy tablet, Oralair®.

Designed in compliance with pharmaceutical production standards, this new site enables incorporation of grass pollen production while ensuring optimum control of raw materials. Stallergenes has developed a unique process for the production and conversion of raw materials into pharmaceutical active ingredients in order to ensure the high quality of its products and meet the increasingly stringent standards of health agencies. The group's personnel, in liaison with local partners including the CEMAGREF public research institute, have set up a groundbreaking collection and production process which is entirely automated. Stallergenes now operates 45 hectares of grass fields. This surface area may rise to between 120 and 150 hectares in the coming years and so enable half of the company's grass pollen needs to be covered within 5 years.

Stallergenes plans to extend the Amilly site and use it to host house dust mite production activities which are currently performed at the main site in Antony.

"Thanks to investments at the Amilly site, Stallergenes, which was already the world's leading producer of house dust mites in the pharmaceutical sector, also becomes leader for grass pollens. These investments and the considerable R&D effort were made in France in liaison with the public scientific bodies which have jurisdiction in the field" declared Albert Saporta, Stallergenes' Chairman and CEO.

ABOUT ORALAIR®

Oralair® is a sublingual allergen immunotherapy tablet aimed at patients suffering from severe allergic rhinoconjunctivitis caused by grass pollens, inadequately controlled using symptomatic treatments.

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*).

Oralair[®], whose clinical development included over 1,800 patients, can boast an irrefutable body of supporting evidence. The short-term efficacy of Oralair[®] has been demonstrated at the appropriate dose of 300 IR during the first season in two clinical trials in adults and children (VO34.04 and VO52.06).

By means of a pharmacodynamic study (V056.07), Stallergenes demonstrated that this tablet's effect on symptoms began as of the first month, without taking rescue medication and whatever the variations in patients' exposure to pollens.

The long-term efficacy of Oralair[®] – after 3 years of treatment – was demonstrated in the VO53.06 long-term phase III clinical trial. The results of the fourth year of this trial demonstrated that Oralair's efficacy was substantially retained one year after the treatment ceased. They validated the concept of pre-co-seasonal desensitisation (treatment taken four months before then throughout the pollen season for three consecutive seasons) and provide Oralair[®] with a major competitive advantage. Due to these results, a request for the extension of the indication on the long-term effect will be filed as a European Mutual Recognition Procedure. In accordance with the recommendations of a committee of independent experts, the clinical trial will continue in 2011 in order to assess the disease modifying effect after two years without treatment.

Oralair[®] was also the subject of a positive Phase III trial in adults in the United States (VO61.08).

ABOUT STALAIR[®]

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

Launched in 2003 in line with directives issued in 2009 by the EMA¹, the programme affords immunotherapy tablets the same level of recognition as standard pharmaceutical products.

Oralair[®] is the first project resulting from this programme. A Mutual Recognition Procedure has been completed in Europe. Marketed in Germany since 2008, it was recently launched in the Netherlands, the Czech Republic, Slovakia, Austria and Italy. It is in the process of being evaluated in other countries.

The second project in the programme is the Actair[®] house dust mite immunotherapy tablet. Having demonstrated the efficacy of Actair[®] after 4 months of treatment and the persistence of its therapeutic effect after only one year of treatment (study VO57.07 conducted in Europe), Stallergenes is now conducting a phase III paediatric study. After consultation with the PEI (Germany biological product regulatory agency), Stallergenes will submit a registration file for Actair[®] with the German health authorities in 2011. Stallergenes plans to market Actair[®] in Germany in late 2012 and in Europe in 2013 further to a Mutual Recognition Procedure.

The Stalair[®] rBet 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. Additional trials are planned.

¹ European Medicine Agency

Ragweed pollen immunotherapy tablets (primarily intended for the US market) as well as those for Japanese cedar pollen (primarily intended for the Japanese market) are at an early stage of development.

In total, the entire Stalair® programme covers 80% of the epidemiology of all markets.

ABOUT STALLERGENES

Stallergenes is a European biopharmaceutical company dedicated to immunotherapy treatments for the treatment of allergy-related respiratory diseases, such as severe rhinoconjunctivitis and rhinitis as well as allergic asthma. A pioneer and leader in sublingual immunotherapy treatments, Stallergenes devotes almost 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 2010, Stallergenes had a turnover of 216 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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