

STALLERGENES

PRESS RELEASE

STALLERGENES IS GRANTED A MARKETING AUTHORIZATION FOR ORALAIR® IN EUROPE

Antony, France (November 27, 2009). Stallergenes has been granted European approval to market Oralair® in both adults and children through a Mutual Recognition Procedure. Germany, the first country where Oralair® has been marketed, was the reference Member state.

Oralair® is now registered in Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, and Spain. All the countries in which Stallergenes filed its application have approved it.

Oralair® is an immunotherapy tablet aimed at patients suffering from severe rhinoconjunctivitis caused by grass pollens, inadequately controlled using symptomatic treatments (antihistamines, corticosteroids).

“The European registration of Oralair® is a major milestone for Stallergenes. It confirms the evolution of immunotherapy towards EBM-documented, well-tolerated treatments, effective from the very first season. Immunotherapy tablets now share the same level of recognition as conventional pharmaceuticals and form a new therapeutic class: allergens. The next step is to implement the price and reimbursement assessment procedures prior to the launch country by country,” says Albert Saporta, Chairman and CEO of Stallergenes.

ABOUT ORALAIR®

The Oralair® active substance consists of a set of pollens 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 (when the treatment is taken all year round). A pharmacodynamic study has demonstrated that Oralair® is effective from the first month of treatment.

The clinical development program for Oralair® is continuing. The results of three phase III clinical studies are expected by the end the year: the US study in adults, the third year of a long-term study, and the protocol optimization study. The long-term results will be available in a year.

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.

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.

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

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