

STALLERGENES

PRESS RELEASE

ORALAIR® GRASSES OBTAINS A PEDIATRIC MA¹ IN GERMANY

Antony, France (January 19, 2009) Stallergenes S.A. today announced that the Paul Ehrlich Institute, the German agency in charge of regulating biological products, has approved its application for a pediatric extension (5-17 years) of the indications for Oralair® Grasses, sublingual tablets for desensitization to grass pollens.

The marketing authorization for adults was granted on June 24, 2008. Oralair® Grasses will therefore be marketed for both indications in Germany for the 2009 pollen season.

Stallergenes will now begin a mutual recognition procedure for registration of the product in Europe for both the adult and pediatric indications, with Germany as the reference member state. The pivotal phase III pediatric trial, VO 52.06², conducted in 278 allergic rhinoconjunctivitis-sufferers aged between 5 and 17 years in 5 European countries (Denmark, France, Germany, Poland, Spain), confirmed the results of the adult trial: an excellent tolerance profile and a statistically and clinically significant reduction in symptoms. The pediatric and adult dosages are identical.

“This new MA¹ for Oralair® Grasses represents an important milestone in the field of pediatric desensitization therapy. Thanks to the quality of the clinical trials conducted during the development of the tablet, grass pollen desensitization therapy has now achieved a level of evidence so far unprecedented in children and in line with the requirements of evidence-based-medicine³. Children are a core target for desensitization therapy, accounting for around 40% of patients.”

“Oralair® Grasses has already been well received in adults: both its price and its pre- and coseasonal position fit squarely with the expectations of German allergy specialists. This EBM-documented, well-tolerated and easy-to-take treatment, which is effective from the very first season, is set to quickly become firmly established for pediatric use”, states Albert Saporta, Chairman and CEO of Stallergenes.

¹ Marketing Authorization

² Wahn U, et al. *Efficacy and safety of 5-grass-pollen sublingual immunotherapy tablets in pediatric allergic rhinoconjunctivitis*. The Journal of Allergy and Clinical Immunology. January 2009 (Vol. 123, Issue 1, Pages 160-166.e3).

³ Evidence-Based Medicine (EBM) is defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett, 1996).

ABOUT ORALAIR® GRASSES

Oralair® Grasses is a tablet for desensitization to grass pollens, the allergen that causes rhinoconjunctivitis and allergic rhinitis in more than 50% of patients in Europe.

With a safe and easy-to-use daily tablet of Oralair® Grasses, patients enjoy a very significant alleviation of all their rhinoconjunctivitis symptoms, a marked reduction in their symptomatic medication use and a noticeable improvement in their quality of life.

Oralair® Grasses has been shown to be effective in rhinoconjunctivitis caused by allergy to grass pollens from the first season, throughout the entire pollen season and during pollen peaks:

- in poly- and mono-sensitized patients and asthmatic patients,
- on every individual symptom, and, in particular, on nasal congestion and watery eyes.

Oralair® Grasses is indicated as a pre- and coseasonal treatment: treatment should be started four months before the pollen season starts and then be maintained throughout the season. Treatment should be repeated, following the same protocol, for 3 consecutive pollen seasons.

Oralair® Grasses contains a mix of five standardized grass pollens, mimicking patients' natural exposure: perennial rye grass (*Lolium perenne*), meadow grass (*Poa pratensis*), timothy grass (*Phleum pratense*), cocksfoot (*Dactylis glomerata*) and sweet vernal grass (*Anthoxanthum odoratum*).

The clinical development program has already enrolled around 1,600 patients to date, including 278 children. A pivotal trial aimed at confirming the long-term efficacy of the treatment is currently under way. In line with the program schedule, the results will be communicated at the end of 2009. Finally, the company is presently carrying out a trial in adults, with a view to registration in the USA.

ABOUT THE ORALAIR DEVELOPMENT PROGRAM

According to World Health Organization (WHO) estimates, 20 to 25% of the world's population suffer from respiratory allergic symptoms (rhinitis and/or asthma). By 2020, 50% of the world's population will be affected by allergy according to the ISAAC study. According to WHO, desensitization is the only treatment that addresses the immunological cause of allergy and modifies the natural course of the disease. Nearly 15 to 20% of these patients suffer from moderate to severe allergic rhinitis and rhinoconjunctivitis, not controlled by their usual medical treatment.

Since 2003, Stallergenes has been running the Oralair program, which addresses these unmet medical needs with EBM-documented, registered allergen tablets that are safe and easy-to-use.

This program consists in the development of tablets for four of the main allergens triggering more than 80% of these allergies: grass pollens, house dust mites, birch pollen and ragweed pollen.

The entire program is in the clinical development stage and is proceeding according to schedule.

ABOUT STALLERGENES

Stallergenes is a European biopharmaceutical company dedicated to desensitization therapies for the prevention and treatment of allergy-related respiratory diseases, such as rhinoconjunctivitis and allergic asthma. A pioneer and leader in sublingual desensitization treatments, Stallergenes devotes 20% of its turnover, in gross terms, to Research and Development and is actively involved in the development of a new therapeutic class: sublingual desensitization tablets.

In 2008, Stallergenes had a turnover of 170,9 million euros and provided desensitization treatments to more than 500,000 patients.

Stallergenes is listed on Euronext Paris (Compartment B) and is part of the sample composing the SBF 120 index.

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

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