## **STALLERGENES**

### PRESS RELEASE

# STALLERGENES OBTAINS A MARKETING AUTHORIZATION FOR ORALAIR® IN AUSTRALIA

**Antony (France), 18 May 2011** - Stallergenes S.A. has announced that the Australian health authority, the Therapeutic Goods Administration (TGA), has approved the grass pollen sublingual immunotherapy tablet Oralair® in adult and pediatric indications.

This registration, which allows patients suffering from severe allergic rhinitis inadequately controlled using symptomatic treatment to benefit more easily from sublingual immunotherapy, leads also to the creation of a Stallergenes subsidiary in Australia. Already present in the country with Staloral<sup>®</sup> and its subcutaneous range distributed by Link Pharmaceuticals, Stallergenes has boosted its position on the Australian allergen immunotherapy market with the launch of Oralair<sup>®</sup>.

"We are delighted about the registration of Oralair® in Australia, which further reinforces the success already achieved by the product in numerous countries and demonstrates how the Stalair® program is contributing to Stallergenes' geographic expansion", said Albert Saporta, Chairman and CEO of Stallergenes. "We are proud to be able to contribute to the development of allergology on this continent, which has fully taken on board the public health problem represented by respiratory allergies. We have good reasons to anticipate a warm welcome of Oralair® from the allergology community. The launch of pharmaceutical specialties will help restructure the Australian allergen immunotherapy market."

This approval marks a new stage in the expansion of Oralair®, which is set to be registered on several other strategic markets by the end of the year.

#### ABOUT RESPIRATORY ALLERGIES IN AUSTRALIA<sup>1</sup>

4.1 million Australians suffer from respiratory allergy, mostly triggered by house dust mites or grass pollens. Allergic rhinitis (25% of the population) and asthma (25% of children, 14% of teenagers) are among the 10 most common diseases among 12-24 year-olds.

According to a report produced by ASCIA<sup>1</sup>, the cost of allergies is 7.8 billion Australian dollars per year (5.8 billion euros)<sup>2</sup>, due to loss of productivity and public health spending.

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<sup>&</sup>lt;sup>1</sup> Australasian Society for Clinical Immunology and Allergy (ASCIA)

<sup>&</sup>lt;sup>2</sup> ASCIA report, Economic Impact of Allergies

The Healthcare Reform Program drawn up in 2008 includes measures related to the treatment of asthma as part of the fight against chronic diseases (diabetes, asthma, heart disease). According to this report, a third of chronic diseases, including asthma, are caused by risky behavior, such as smoking, obesity and a lack of physical exercise. The report proposes trying to reduce the prevalence of these exogenous factors responsible for the poor health of many Australians.

#### **ABOUT STALAIR®**

Stalair<sup>®</sup> is the name of the pharmaceutical and clinical development program for sublingual immunotherapy tablets being implemented by Stallergenes with a view to obtaining marketing authorizations for pharmaceutical products in Europe and other strategic markets.

The program, launched in 2003 and fitting squarely with the guidelines issued in 2009 by the EMA<sup>3</sup>, brings immunotherapy tablets the same level of recognition as conventional pharmaceutical products.

Oralair® is the first product resulting from this program. A Mutual Recognition Procedure has been successfully completed in Europe. Marketed in Germany since 2008, it has recently been launched in the Netherlands, the Czech Republic, Slovakia, Austria, Italy and Spain. It is currently being evaluated in other countries.

The second project in the program is the house dust mite immunotherapy tablet, Actair<sup>®</sup>. Having demonstrated the efficacy of Actair<sup>®</sup> 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 study in children. Following consultations with the PEI<sup>4</sup>, Stallergenes will file a registration application for Actair<sup>®</sup> with the German health authorities in 2011. Stallergenes plans to market Actair<sup>®</sup> in Germany at the end of 2012 and thereafter in the rest of Europe.

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 studies are required. The immunotherapy tablets for allergy to ragweed pollen (aimed primarily at the US market) and Japanese cedar pollen (aimed primarily at the Japanese market) are at an early stage of development.

Altogether, the Stalair® program covers 80% of the epidemiology for all markets.

#### **ABOUT LINK PHARMACEUTICALS**

Link Pharmaceuticals is focused on marketing a diverse range of specialist and vitally important therapeutic products in Australia and New Zealand.

The Company's success is based on a decade of strong performance from the Pharmaceutical Division which has developed an impressive portfolio of acquired and in-licensed therapeutic products.

With headquarters in Sydney and regional office in Auckland, Link Pharma provides an excellent service to both our customers and commercial partners.

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<sup>&</sup>lt;sup>3</sup> European Medicines Agency

<sup>&</sup>lt;sup>4</sup> Paul Ehrlich Institute, German agency regulating biological products

#### **ABOUT STALLERGENES**

Stallergenes is a European biopharmaceutical company dedicated to the treatment of allergy-related respiratory diseases, such as severe rhinoconjunctivitis and rhinitis, as well as allergic asthma, using allergen immunotherapy. The seventh largest pharmaceutical company in France and sublingual immunotherapy treatment leader, 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, the company 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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