

**PRESS RELEASE****STALORAL<sup>®</sup> MITES 300 CLINICAL STUDY IN CHINA:****THE EFFICACY OF SUBLINGUAL ALLERGEN IMMUNOTHERAPY  
DEMONSTRATED IN MODERATE ASTHMA  
DUE TO MITES**

**Antony, France (June 21, 2010).** Stallergenes S.A. announces the results of a phase III clinical trial (VO55.06) conducted in China aimed at assessing the efficacy and safety of sublingual immunotherapy (Staloral<sup>®</sup> mites 300) in adult patients suffering from asthma triggered by house dust mites.

Study VO55.06 is a phase III randomized, double-blind, placebo-controlled study conducted over a period of 15 months in 14 centers located in China's main cities. After an observation period of 3 months, 484 adult patients with mild to moderate asthma well controlled under inhaled corticosteroid therapy were divided into two groups, one treated with Staloral<sup>®</sup> 300 and one given a placebo for a period of 12 months. Throughout the duration of the study, the patients received inhaled corticosteroid therapy at gradually reduced dosages. The patients were assessed on the basis of the level of asthma control as defined by GINA<sup>1</sup>.

Staloral<sup>®</sup> 300 demonstrated statistically significant efficacy versus placebo for the control of asthma, on the basis of the following criteria: "well-controlled asthma" and "totally controlled asthma" in GINA 3 patients (moderate asthma stabilized with corticosteroids by bronchial route). In this population, the probability of a patient having his/her asthma well or totally controlled is more than twice as high with Staloral<sup>®</sup> 300 as it is in the placebo group (odds ratios and 95% confidence intervals of 2.10 [1.01; 4.36] and 2.43 [1.28; 4.61] respectively).

The treatment was well tolerated. There were no pulmonary side effects related to worsening of asthma or deterioration in lung function.

"We are very pleased with the outstanding outcomes of this large-scale study, conducted in China with a solid methodology. They pave the way for better asthma management and improved quality of life for patients", emphasizes Prof. YIN Jia, Principal Coordinator and Head of the Allergy Department at the Peking Union Medical College Hospital and President of the Chinese Allergology Society.

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<sup>1</sup> GINA : Global Initiative on Asthma.

GINA, in collaboration with the National Heart, Lung, and Blood Institute, National Institute of Health, USA, and the World Health Organization, is elaborating and updating the worldwide consensus on asthma management. GINA has defined 4 levels of asthma from mild (1) up to severe (4).

“For the first time, the efficacy of sublingual allergen immunotherapy has been demonstrated in the stabilization of allergic asthma due to mites in adults through a large-scale clinical trial. This very good outcome will enable us to apply for registration of Staloral<sup>®</sup> mites 300 in China in the near future. Obviously, these results will lead the clinical development program for Actair<sup>®</sup>, our sublingual immunotherapy tablet for the treatment of allergic rhinitis triggered by dust mites, to also focus on the treatment of asthma in patients allergic to mites”, adds Albert Saporta, Chairman and CEO of Stallergenes.

## **ABOUT ALLERGIC ASTHMA**

Asthma is a chronic inflammatory disease of the airways, very often linked to allergic rhinitis: 80% of allergic asthma sufferers also have allergic rhinitis and 40% of patients with untreated rhinitis go on to develop asthma.

Particularly common in children, asthma is a major public health problem. The frequency of the condition varies from one country to another; in the great majority of developed countries, between 5 and 15% of the adult population and 3 to 7% of the pediatric population are affected. The prevalence of asthma has been gradually increasing over the last 20 years in industrialized countries, at a rate of around 5% per year.

## **ABOUT RESPIRATORY ALLERGY IN CHINA**

The prevalence of respiratory allergy in China ranges from 10 to more than 20% of the population. The most commonly reported related conditions are asthma (9.2%), rhinosinusitis (13.3%) and atopic dermatitis (16.4%). In urban populations, 2 out of 3 allergic rhinitis sufferers are consulting a physician, and 40% of these will have allergen tests.

China is one of the countries offering the greatest potential for economic growth globally in the medium term. It is among the top ten pharmaceutical markets in the world and is well on the way to entering the top 5 by 2011<sup>2</sup>.

## **ABOUT STALORAL<sup>®</sup> 300**

Staloral<sup>®</sup> 300 is a sublingual solution of allergen extracts for allergen immunotherapy. It is indicated in the treatment of seasonal or perennial allergic rhinitis, rhinoconjunctivitis and allergic mild to moderate asthma in adults and children over the age of 5 years. Prescribed by allergy specialists, Staloral<sup>®</sup> 300 is particularly aimed at patients suffering from severe allergic diseases inadequately controlled despite the use of symptomatic treatments.

## **ABOUT ACTAIR<sup>®</sup>**

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

Actair<sup>®</sup> was the subject of a positive IIb/III trial in allergic rhinitis in adults in the first half of 2009. A phase III pediatric trial has been launched.

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<sup>2</sup> IMS Health, Market Prognosis, March 2009 – classification in constant US\$

## 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 more than 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, Stallergenes had a turnover of 193 million euros and more than 500,000 patients were treated with Stallergenes immunotherapy products.

Euronext Paris (Compartment B)  
SBF 120.

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