

## PRESS RELEASE

### STALLERGENES AND SHIONOGI SIGN EXCLUSIVE PARTNERSHIP AGREEMENTS FOR IMMUNOTHERAPY TABLETS IN JAPAN

**Antony, France (September 6, 2010).** Stallergenes S.A. has announced today the signing of exclusive partnership agreements with Shionogi & Co., Ltd. for two sublingual allergen immunotherapy tablet products resulting from the Stalair<sup>®</sup> program: Actair<sup>®</sup> house dust mite tablets and Japanese cedar pollen tablets.

With 32 million respiratory allergy sufferers, there is a strong – and as yet unmet – demand for treatment in Japan, where sublingual allergen immunotherapy is currently not available. House dust mites and Japanese cedar pollen are the two main causes of respiratory allergies and the Japanese cedar allergy is a major public health concern in the country. This partnership is the first of its kind in Japan and will bring sublingual immunotherapy to patients suffering from severe allergic rhinitis, inadequately controlled using symptomatic treatments (antihistamines, corticosteroids).

The agreement covers the development, registration, promotion and distribution of Actair<sup>®</sup> in Japan and Taiwan, and of the Japanese cedar pollen tablet in Japan. The clinical development of Actair<sup>®</sup> will be launched in 2011 in order to prepare the license application. For the Japanese cedar pollen tablet, a specific development plan will be initiated through close collaboration between the two partners, since the product is exclusively aimed at the Japanese market.

Stallergenes will receive:

- an immediate upfront payment of Euros 24 million,
- up to Euros 46 million in development and regulatory milestones payments,
- as well as sales milestones.

Furthermore, Stallergenes will be entitled to royalty payments on net sales of the products by Shionogi & Co., Ltd.

Shionogi & Co., Ltd. will be responsible for the clinical development, registration, marketing and sales of the products covered by this agreement in Japan. Stallergenes will be responsible for tablet production and supply, and early-stage development.

“We are enthusiastic about the prospect of collaborating with Stallergenes, the world leader in sublingual allergen immunotherapy, and are very looking forward to bringing new treatment options of sublingual immunotherapy to a huge number of allergic rhinitis patients in Japan, most of whom suffer from allergy to house dust mite and/or Japanese cedar,” declared Dr. Isao Teshirogi, President of Shionogi & Co., Ltd.

“We are delighted to team up with Shionogi & Co., Ltd., one of Japan’s biggest pharmaceutical companies, an R&D-based organization and a key player in the allergy field. Shionogi & Co., Ltd.,

thanks to its strong allergy franchise and its well-established presence alongside allergy specialists, and Stallergenes will develop immunotherapy in Japan, particularly for house dust mite allergy, in which it has recently demonstrated its efficacy after 4 months of treatment and the persistence of its therapeutic effect after only one year of treatment,” declared Albert Saporta, Stallergenes’ Chairman and CEO.

## **ABOUT RESPIRATORY ALLERGY IN JAPAN**

Allergic rhinitis affects 25%<sup>1</sup> of the population in Japan, and asthma 6.7%<sup>2</sup>. House dust mites and Japanese cedar pollen are the two main causes of respiratory allergies.

The Japanese allergy market is the 2<sup>nd</sup> biggest in the world behind the USA. There is a very strong – and as yet unmet - demand for allergy treatments in Japan.

## **ABOUT THE STALAIR<sup>®</sup> PROGRAM**

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

The Stalair<sup>®</sup> development program includes 5 immunotherapy tablets: Oralair<sup>®</sup> (grass pollen), Actair<sup>®</sup> (house dust mites), r Bet v 1 (birch pollen recombinant allergen), ragweed pollen and Japanese cedar pollen.

Oralair<sup>®</sup> is the first project resulting from this program. A Mutual Recognition Procedure has been completed in Europe. Oralair<sup>®</sup>, which is already marketed in Germany, will be launched in the fall in the Netherlands, the Czech Republic, Slovakia and Austria. Having recently demonstrated its efficacy after 3 years of treatment (study VO53.06 conducted in Europe), Oralair<sup>®</sup> has been the subject of a positive phase III trial in adults in the United States (VO61.08).

The second project in the program is Actair<sup>®</sup>, house dust mite immunotherapy tablet. Having recently demonstrated Actair<sup>®</sup> efficacy 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 preparing filing NDA in Germany. A phase III pediatric study has been launched.

The Stalair<sup>®</sup> r Bet 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. A confirmatory phase III study is currently being prepared with a view to EMA registration.

The ragweed pollen and Japanese cedar pollen tablets are at an early stage of development.

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

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<sup>1</sup> Sakurai Y, Nakamura K, Teruya K, Shimada N, Umeda T, Tanaka H, Yoshizawa N. Prevalence and risk factors of allergic rhinitis and cedar pollinosis among Japanese men. *Prev Med.* 1998 Jul-Aug;27(4):617-22.

<sup>2</sup> Masoli M, Fabian D, Holt S, Beasley R; Global Initiative for Asthma (GINA) Program. The global burden of asthma: executive summary of the GINA Dissemination Committee report. *Allergy.* 2004 May;59 (5):469-78.

## ABOUT SHIONOGI & CO.,LTD

Headquartered in Osaka, Japan, Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on patients. Shionogi's Research and Development currently targets three therapeutic areas: Infectious Diseases, Pain, and Metabolic Syndrome. The Company is the originator of innovative medicines which have been successfully delivered to millions of patients worldwide. In addition, Shionogi is engaged in new research areas such as allergy and cancer. Contributing to the health of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit [www.shionogi.co.jp](http://www.shionogi.co.jp).

## 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.

A pioneer and leader in sublingual immunotherapy treatments, Stallergenes dedicates 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.

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

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