

## PRESS RELEASE

# STALLERGENES REPORTS POSITIVE RESULTS IN THE PHASE II / III CLINICAL TRIAL OF HOUSE DUST MITE IMMUNOTHERAPY TABLETS IN JAPAN

**Antony (France), 3 February 2014** – STALLERGENES S.A (Euronext Paris) today announced the completion of a phase II / III clinical study (S-524101) of its sublingual immunotherapy tablet for the treatment of house dust mites related allergic rhinitis, conducted in Japan by its partner Shionogi & Co. Ltd..

The randomized, double-blind and placebo-controlled S-524101 study evaluated the efficacy and safety of a 12 month course of treatment. Shionogi reported that the study achieved its primary efficacy endpoint, as the treated groups have demonstrated a statistically significant difference on the Average Adjusted Symptom Score over one year of treatment versus the placebo group. Overall, the safety and tolerability profile were favorable.

"We are very pleased with the results of this study, which represent an important step forward in the clinical development of our house dust mite sublingual immunotherapy tablet in Japan", said Roberto Gradnik, Chief Executive Officer of STALLERGENES. "This represents a major achievement resulting from our successful partnership with Shionogi & Co. Ltd., which may lead to Japanese allergy sufferers having access to new and innovative solutions".

A New Drug Application (NDA) in Japan is planned within the first half of the next Japanese fiscal year (ending March 2015).

In September 2010, STALLERGENES signed exclusive partnership agreements with Shionogi & Co., Ltd for the clinical development, registration, marketing and sales of sublingual house dust mite immunotherapy tablets and sublingual Japanese cedar pollen immunotherapy tablets. On this occasion, STALLERGENES received an upfront payment of Euros 24 million and may receive additional development and regulatory milestones payments of up to Euros 46 million, as well as sales milestones. STALLERGENES is also entitled to royalty payments on net sales of the products by Shionogi & Co., Ltd..

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#### **ABOUT RESPIRATORY ALLERGY IN JAPAN**

Allergic rhinitis affects 25% <sup>1</sup> of Japan's population and asthma 6.7% <sup>2</sup>. House dust mites and Japanese cedar pollen are the two main causes of respiratory allergies. From early childhood, house dust mites can trigger allergic rhinitis, which worsens over time with a natural progression towards asthma. The symptoms may be severe, significantly impairing patients' quality of life.

With 32 million respiratory allergy sufferers, there is a strong, and as yet unmet – demand for allergy treatment in Japan, where sublingual allergen immunotherapy is not currently available.

### **ABOUT STALLERGENES**

STALLERGENES is an international biopharmaceutical company dedicated to the treatment of allergy-related respiratory diseases, such as severe rhinoconjunctivitis and rhinitis, as well as allergic asthma, using allergy immunotherapy. The leader in sublingual immunotherapy treatments, STALLERGENES devotes around 20% of its annual gross revenues to Research & Development and is actively involved in the development of a new therapeutic class: sublingual immunotherapy tablets. In 2012, the Company generated revenues of € 240 million, and more than 500,000 patients were treated with STALLERGENES products.

Euronext Paris (Compartment B)

CAC small

ISIN: FR0000065674 Reuters: GEN.PA Bloomberg: GEN.FP



#### Additional information is available at <a href="http://www.stallergenes.com">http://www.stallergenes.com</a>

Forward-looking statements related to Stallergenes

This press release may contain forward-looking statements, including forecasts of future revenue and operating profit as well as expected business-related events. Such statements are based upon the current beliefs and expectations of Stallergenes' management and are subject to risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements, due to various factors. Without being exhaustive, such factors include economic situations and business conditions, including legal and product evaluation issues, fluctuations in currencies and demand, changes in competitive factors and reliance on suppliers. The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information or future events and except as required by law.

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<sup>&</sup>lt;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>&</sup>lt;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.