

## PRESS RELEASE

### **STALLERGENES ANNOUNCES THE APPROVAL IN JAPAN OF STG320, THE FIRST SUBLINGUAL IMMUNOTHERAPY TABLET FOR THE TREATMENT OF HOUSE DUST MITE ALLERGY**

**STG320 is the first house dust mite immunotherapy tablet ever  
to obtain a Marketing Authorization in the world**

**Antony (France), 30 March 2015** – STALLERGENES S.A. (Euronext Paris), a global healthcare company specialized in the diagnosis and treatment of allergies through allergy immunotherapy, announced today that its partner, Shionogi & Co., Ltd has received the approval of STG320 from the Japanese health authorities (PMDA - Pharmaceuticals and Medical Devices Agency). STG320 is the first immunotherapy tablet registered in Japan for the treatment of house dust mite induced allergic rhinitis.

"This approval marks a milestone for STALLERGENES and its STG320 clinical development programme, as it is the first regulatory approval received worldwide for a house dust mite allergy immunotherapy tablet. It clearly shows that health authorities recognize the quality and therapeutic value of the tablet developed by STALLERGENES", stated Christian Chavy, Chief Executive Officer of STALLERGENES. "While market access conditions for STG320 are still under discussion, the approval of STG320 is further proof of the successful long-term collaboration between STALLERGENES and Shionogi & Co., Ltd."

Since September 2010, Shionogi & Co., Ltd has been the exclusive partner of STALLERGENES for the clinical development, registration, marketing and sales of sublingual house dust mite immunotherapy tablets and sublingual Japanese cedar pollen immunotherapy tablets. The approval of STG320 triggers the payment by Shionogi & Co., Ltd of €10 million to STALLERGENES. STALLERGENES will also receive compensation on sales of STG320 in Japan.

#### **ABOUT THE DEVELOPMENT OF STG320 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 in this country. STG320 has been the subject of a phase II / III clinical study in Japan (S-524101). This randomized, double-blind and placebo-controlled study has evaluated the efficacy and safety of a 12 month course of treatment with sublingual house dust mites immunotherapy tablets. On 3 February 2014, Shionogi reported that the study achieved its primary efficacy endpoint, as the treated groups have

<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.

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 favourable.

## ABOUT STALLERGENES

STALLERGENES is a global healthcare company specialized in the diagnosis and treatment of allergies. For more than 50 years, STALLERGENES has been continuously expanding the existing frontiers of science in order to provide allergy patients with more effective long lasting therapeutic options. Thanks to its innovation strategy, fuelled by investments in research and development amounting to around 20% of total annual revenues as well as external partnerships, STALLERGENES is able to provide targeted allergen immunotherapy-based allergy solutions that significantly improve the lives of allergy patients around the world.

STALLERGENES operates in 21 countries and employs over 1,000 people. In 2014, the Company generated total revenues of €251 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 [www.stallergenes.com](http://www.stallergenes.com)

### *Forward-looking statements related to Stallergenes*

*This press release may contain forward-looking statements, including targets for 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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