

# **PRESS RELEASE**

# STALLERGENES ANNOUNCES FDA ACCEPTANCE FOR REVIEW OF ITS BLA FOR ORALAIR, 5-GRASS POLLEN EXTRACT AIT SUBLINGUAL TABLET

**Antony, France, 18 February 2013** – Stallergenes S.A. (Euronext Paris CAC small) today announces that FDA has accepted for review its Biologics License Application (BLA) for Oralair, its 5-grass pollen extract allergen immunotherapy (AIT) sublingual tablet.

This BLA filing represents an important step towards the future launch of Oralair in the US market and positions Stallergenes as the first pharmaceutical company to file and have FDA acceptance to review a BLA for an AIT sublingual tablet in this market.

"We are delighted about the acceptance of our BLA filing for our tablet in the USA which is fully consistent with our drive for innovation and is a major step in Stallergenes' international growth strategy. We are looking forward to working with the FDA towards the approval", said Roberto Gradnik, Chief Executive Officer.

Stallergenes' AIT sublingual tablet is a pharmaceutical product marketed as Oralair in Europe and in some other international markets for the treatment of grass pollen allergy. Marketed in Europe since 2008, Oralair is the only sublingual AIT tablet composed of 5-grass pollen extract which corresponds to the epidemiological exposure of patients. It is available for patient self-administration with a precoseasonal protocol.

# **ABOUT ORALAIR**

Oralair is an allergen immunotherapy sublingual tablet consisting of five purified and calibrated pollen extracts: Perennial Ryegrass (Lolium perenne), Kentucky Bluegrass (Poa pratensis), Timothy Grass (Phleum pratense), Orchard Grass (Dactylis glomerata) and Sweet Vernal Grass (Anthoxanthum odoratum).

To date, Oralair is available in 16 European countries and also continues to expand beyond Europe: following a positive start in Australia/New Zealand and Russia, the product was launched a few months ago in Canada, which makes it the first allergen immunotherapy tablet to be registered and marketed in North America.

#### ABOUT THE US ALLERGEN IMMUNOTHERAPY MARKET

The US market offers substantial potential for the development of sublingual immunotherapy: allergic rhinitis affects 60 million people and the most prevalent allergen is grass pollen.

Today, less than 3 million allergy sufferers are treated by allergen immunotherapy, i.e. 5% of the US allergic population. The current standard of care in the USA for immunotherapy is multiple injections of allergens performed in a supervised medical setting. There is therefore a strong need for an innovative sublingual treatment in the USA, as currently approved allergen immunotherapy is not available for patient self-administration.

#### **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 allergen immunotherapy. The leader in sublingual immunotherapy treatment, Stallergenes devotes around 20% of its annual gross sales to Research & Development and is actively involved in the development of a new therapeutic class: sublingual immunotherapy tablets.

In 2012, the company generated sales of €243 million, and more than 500,000 patients were treated with Stallergenes products.

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

# 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.

#### **Contacts:**

Roberto Gradnik, Chief Executive Officer Tel. +33 1 55 59 20 04

# Investor and analyst relations

Christian Thiry Chief Financial Officer Tel. +33 1 55 59 20 95

e-mail: investorrelations@stallergenes.com

#### **Press Relations**

Lise Lemonnier,

Senior Communication & Public Affairs Director

Tel. + 33 1 55 59 20 96

e-mail: llemonnier@stallergenes.com

# Investor and press relations agency:

F T I Consulting – Press contact Emmanuelle Flobert Tel. +33 1 47 03 68 56 emmanuelle.flobert@fticonsulting.com FTI Consulting – Analyst and investor contact Stéphanie Bia Tel. +33 1 47 03 68 16 stephanie.bia@fticonsulting.com