STALLERGENES

# **PRESS RELEASE**

# STALLERGENES CONTINUES ITS STRATEGIC INTERNATIONAL EXPANSION WITH THE SUCCESSFULL REGISTRATION IN CANADA OF ORALAIR™ TABLET FOR GRASS POLLEN

Antony (France), 21 March 2012 - Stallergenes SA (Euronext Paris CAC small) announced today that Health Canada has approved Oralair<sup>TM</sup>. Oralair<sup>TM</sup> is a sublingual grass pollen immunotherapy tablet for the treatment of moderate to severe seasonal grass pollen allergic rhinitis with or without conjunctivitis.

With this approval, Oralair<sup>™</sup> becomes the first allergen immunotherapy tablet to be registered in North America.

"We are delighted that Oralair<sup>™</sup> has received regulatory approval in Canada. This approval confirms the strength of our clinical data and is a good base to continue together with our partner Paladin Labs the success already achieved by the product in other markets. It also demonstrates Stallergenes' strategy to strengthen its international expansion" said Roberto Gradnik, Chief Executive Officer of Stallergenes SA.

The prevalence of respiratory allergy in Canada is estimated to be similar to European rates, approximately 20% to 25% of the adult Canadian population, among which 50% would be allergic to grass pollen<sup>1</sup>. The current standard of care in Canada for grass allergy immunotherapy is multiple injections of grass pollen allergens performed in a doctor's office. Oralair<sup>™</sup> is a sublingual tablet which can be taken in the comfort of one's own home and has an unmatched safety profile. Oralair<sup>™</sup> efficacy has been demonstrated through seven placebo controlled clinical trials involving more than 2,600 patients from Europe and North America.

"We are pleased and excited that Health Canada has granted regulatory approval for Oralair<sup>™</sup>, said Mark Beaudet, interim President and Chief Executive Officer of Paladin Labs Inc. (TSX: PLB). "We anticipate launching Oralair<sup>™</sup> in time for the 2013 allergy season and are confident that, when launched, Oralair<sup>™</sup> will provide Canadian allergy sufferers with a safe, effective and convenient alternative for the treatment of seasonal grass allergies."

Oralair<sup>™</sup> has been marketed in Europe since 2008 and is now approved in 27 countries.

<sup>&</sup>lt;sup>1</sup> Bauchau V, Durham SR. Prevalence and rate of diagnosis of allergic rhinitis in Europe. Eur Respir J 2004;24:758-64

## **ABOUT ORALAIR™**

Oralair<sup>™</sup> is a sublingual immunotherapy tablet consisting of five pollen extracts corresponding to the epidemiological characteristics of patient exposure: rye grass (Lolium perenne), meadow grass (Poa pratensis), timothy grass (Phleum pratense), cocksfoot (Dactylis glomerata) and sweet vernal grass (Anthoxanthum odoratum).

#### Oralair<sup>™</sup> Indication

Oralair<sup>™</sup> is indicated for the treatment of grass pollen allergic rhinitis with or without conjunctivitis in adults, adolescents and children above the age of 5, with clinically relevant symptoms, confirmed by a positive cutaneous test and/or a positive titre of the specific IgE, who have not adequately responded to, or tolerated, conventional pharmacotherapy.

## Oralair™ Dosing Regimen

Oralair<sup>™</sup> is administered once daily pre-seasonally (4 months prior pollen season) and coseasonally (during pollen season). Although the grass pollen season varies geographically, typically patients will begin their therapy in January and continue until July.

Titration phase is completed in 3 days (1 tablet of 100 IR, 2 tablets of 100 IR, 1 tablet of 300IR) and maintenance phase is completed with 1 tablet of 300IR until the end of the season.

A pharmacodynamic study has demonstrated that Oralair<sup>™</sup> is effective from the first month of treatment. The post treatment long-term efficacy of Oralair<sup>™</sup> as a discontinuous treatment according to a pre- and coseasonal scheme – after 3 years of treatment – was demonstrated in the VO53.06 long-term phase III clinical trial in European and Canadian centers.

#### Who Should Prescribe Oralair™?

Treatment with Oralair<sup>™</sup> should only be prescribed and initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.

# ABOUT PALADIN LABS

Paladin Labs Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products. With this strategy, a focused national sales team and proven marketing expertise, Paladin has evolved into one of Canada's leading specialty pharmaceutical companies. For more information, please visit the Company's web site at www.paladinlabs.com

#### ABOUT STALLERGENES

Stallergenes is a European biopharmaceutical company dedicated to the treatment of allergyrelated respiratory diseases, such as severe rhinoconjunctivitis and rhinitis, as well as allergic asthma, using allergen immunotherapy. The seventh largest pharmaceutical company in France and the leader in sublingual immunotherapy treatment, Stallergenes devotes almost 20% of its gross turnover to Research & Development and is actively involved in the development of a new therapeutic class, sublingual immunotherapy tablets.

In 2011, the company had a turnover of 235 million euros, 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.

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