

**PRESS
RELEASE****IMMUNOTHERAPY TABLET
CONTAINING RECOMBINANT ALLERGEN (rBet v 1)
OF BIRCH POLLEN:
POSITIVE RESULTS FOR A PHASE IIb/III TRIAL**

Antony, France (September 16, 2009) Stallergenes S.A. has announced the first results of a new phase IIb/III clinical trial (VO59.08) conducted in allergic rhinitis caused by birch pollen and concerning the development of a sublingual immunotherapy tablet containing the recombinant allergen of this pollen, rBet v 1.

This study is the first ever to use a recombinant allergen as an active substance. To Stallergenes' knowledge, the use of a recombinant protein in dry form is also a world first.

The VO59.08 study, conducted during the 2009 pollen season, was a randomized, double-blind, placebo-controlled trial. It included 483 adult patients allergic to birch pollen and suffering from rhinoconjunctivitis symptoms in 30 centers in 8 different countries. The patients were divided into 4 groups: 3 groups treated with sublingual tablets containing 12.5 µg, 25 µg and 50 µg of rBet v 1, respectively, with no dose-titration phase, and one group receiving placebo.

The primary endpoint for analysis of the results was the reduction in average adjusted symptom score (AASS). The 3 treated groups demonstrated a statistically significant reduction in AASS in comparison with placebo ($0.002 < p < 0.03$) of approximately 25% over the season as a whole and approximately 30% at its peak. The overall tolerance was very good, notably for the 12.5 µg and 25 µg dosages.

"This study conducted by Stallergenes marks a very important milestone in immunotherapy. It is the first time that clinical development with a regulatory objective has been undertaken with a recombinant allergen. Analysis of all the results should make it possible to select the optimum dose and to define the conditions for the confirmatory phase III study that will be conducted with a view to filing a centralized marketing authorization application with the EMEA.

The rBet v 1 program, launched in 2003 with the signature of a licensing agreement for rBet v 1 produced by Biomay, has represented an unprecedented pharmaceutical development effort, together with our manufacturing partner CMC Biologics" says Albert Saporta, Chairman and CEO of Stallergenes.

"We are excited and proud to be part of the rBet v 1 innovative program. As a partner to Stallergenes, CMC is committed to the challenge of producing the world first major recombinant allergens on a large scale" says David Kauffmann, Chairman of CMC Biologics.

ABOUT BIRCH POLLEN ALLERGY

Very common in Northern Europe – and especially Germany, the Netherlands, Norway, Sweden and Switzerland, the prevalence of allergic rhinitis caused by birch pollen exceeds 20% in some large cities¹.

The birch pollen season is short – lasting just 1 to 2 months – but intense, and precedes the grass pollen season.

ABOUT THE STALAIR® PROGRAM

Stalair® is the pharmaceutical and clinical development program for immunotherapy being implemented by Stallergenes with a view to obtaining registrations for pharmaceutical products in Europe and, via partnership agreements, with strategic markets outside Europe.

The first tablet resulting from this program, Oralair® (grass pollen immunotherapy tablet), is available in Germany for adults and children. This tablet is currently being evaluated in other European countries.

The dust mite immunotherapy tablet, Actair® was the subject of a phase IIb/III study in allergic rhinitis in adults during the first half of 2009. A pediatric study has been launched.

Phase IIb/III of the rBet v 1 tablet program has just been completed therefore.

The other allergens concerned by the program are ragweed for the North American market and Japanese cedar pollen for the Japanese market. All together, the program covers 80% of the epidemiology for all markets.

ABOUT BIOMAY

Biomay has more than two decades of expertise in the expression, purification and characterization of recombinant allergens. Biomay offers these allergens off-the-shelf at two quality levels: research-grade and GMP-grade for the production of therapies

Further information about Biomay is available online at: www.biomay.com

ABOUT CMC BIOLOGICS

CMC Biologics is a leading player, in offering integrated services for development and production of biopharmaceutical products. The Company specializes in process development and large-scale manufacturing of pharmaceutical proteins, in compliance with the most stringent cGMP standards, for use in preclinical studies, clinical trials and large-scale commercialization. CMC Biologics offers a broad range of services, including the development of cell lines, development processes, formulations and analytical tests. CMC Biologics has manufacturing sites in Copenhagen, Denmark and Washington, USA.

Further information about CMC Biologics is available online at: www.cmcbio.com

ABOUT STALLERGENES

Stallergenes is a European biopharmaceutical company dedicated to immunotherapy treatments for the prevention and treatment of allergy-related respiratory diseases, such as

¹ Bousquet J. et al. Geographical variation in the prevalence of positive skin prick tests to environmental aeroallergens in the European Community Respiratory Health Survey I. *Allergy* 2007; 62: 301-309.

allergic rhinoconjunctivitis, rhinitis and asthma. A pioneer and leader in sublingual immunotherapy treatments, Stallergenes devotes 21% 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 2008, Stallergenes had a turnover of 171 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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