

PRESS RELEASE**STALLERGENES HAS IDENTIFIED TWO CANDIDATE BIOMARKERS
OF EARLY EFFICACY OF ALLERGEN IMMUNOTHERAPY**

Antony (France), 2 April 2012 – Stallergenes SA (Euronext Paris CAC small) today announced the publication¹ in the April issue of Journal of Allergy and Clinical Immunology (JACI) of an article presenting the identification of two candidates as biomarkers of early efficacy of allergen immunotherapy (AIT) as the hallmark of a regulatory innate immune response predictive of clinical tolerance.

AIT is considered to be the only etiologic treatment for allergic respiratory diseases such as allergic rhinitis. The sublingual route has become widely applied over the last two decades, instead of the historical route of administration consisting of subcutaneous injections. Despite the significant advances of the past few years, the exact immunological mechanisms by which sublingual immunotherapy induces tolerance against allergens in humans remain, however, unclear² and there is currently a great interest in identifying relevant biomarkers which would allow objectively measuring response to immunotherapy in clinical trials and daily practice³.

The article, entitled “A regulatory dendritic cell signature correlates with the clinical efficacy of allergen-specific sublingual immunotherapy” was published today in the Journal of Allergy and Clinical Immunology (JACI). Within the framework of the biomarker research program led by Stallergenes, the objective was to investigate whether markers of effector and regulatory dendritic cells (DCs) were affected during AIT in relationship with clinical benefit, with the assumption that the molecular changes at the level of DCs could be used for response-monitoring at the early stages of allergen immunotherapy. The expression of the markers was assessed by using quantitative Polymerase Chain Reaction (PCR) in peripheral blood mononuclear cells (PBMCs) from 79 patients with grass pollen allergy enrolled in a double-blind, placebo-controlled clinical study evaluating the efficacy of sublingual tablets in an allergen exposure chamber over a 4-month period.

Findings from the study showed that the expression of Complement component 1 (C1Q) and Stabilin-1 (STAB1) was significantly increased in PBMCs from responders to AIT vs. those from non responders to AIT or placebo-treated patients. The study concluded that the expression of these two proteins correlates with clinical tolerance induced by AIT, suggesting a critical role of regulatory immune responses and that therefore C1Q and STAB1 represent candidate biomarkers of early efficacy of AIT.

¹ doi:10.1016/j.jaci.2012.02.014

² Akdis C.A. et al. Immunological mechanisms of sublingual immunotherapy. Allergy Volume 61, Issue Supplement s81, pages 11–14, July 2006

³ Till, S. (2011), Mechanisms of immunotherapy and surrogate markers. Allergy, 66: 25–27.

“We’re very pleased with these initial data showing the potential for two biomarkers,” stated Philippe Moingeon, PhD, Vice President research and pharmaceutical development from Stallergenes. “Once their validity confirmed in larger studies, such biomarkers for short-term efficacy easily detected in peripheral blood could allow the development of new diagnostic tests for better follow-up of patients in daily practice and even the development of new allergy treatments.”

“Stallergenes has been considerably investing in a research program over the past years to identify biomarkers which would be used for response monitoring or as prognostic indicators for sublingual immunotherapy,” indicated Roberto Gradnik, Chief Executive Officer of Stallergenes. “We’re very excited about these data which clearly represent a significant milestone in the scientific history of AIT, as they show potential for a new category of molecules as biomarkers, and look forward to continuing to progress with the confirmation of these findings.”

ABOUT STALLERGENES

Stallergenes is a European 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 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.

Euronext Paris (Compartiment B)
CAC small
Code ISIN : FR0000065674
Code Reuters : GEN.PA
Code Bloomberg : GEN.FP



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

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