



## POSITIVE RESULTS OF STUDY RECOMBINANT Bet v 1

Successful proof of concept study of recombinant Bet v 1 efficacy in desensitization against birch pollen allergy

### Objective:

Birch pollen is one of the most frequent cause of Respiratory Allergy in Central Europe, Northern Europe and Northern America.

Aim of the DV08.01 study was to demonstrate:

1. desensitization based on major allergen (Bet v 1) is as effective and safe as current marketed total extract;
2. recombinant Bet v 1 is as effective and safe as purified natural Bet v 1

### Study Plan

Subcutaneous administration was used. DV08.01 study was a randomized, double blinded, comparative study versus placebo conducted in 5 European countries (150 randomized patients). Length of study was 3 years (2003: baseline – 2004 and 2005: treatment).

Patients were randomized in 4 groups: commercial extract, recombinant Bet v 1 and purified natural Bet v 1 (active groups) and placebo.

### Results

The 3 active groups showed very significant improvement of rhino conjunctivitis symptoms versus placebo after year 1 of desensitization as well as after year 2 (>50%;  $p < 0.001$ ).

In these 3 active groups, very significant reduction of rescue medication usage was demonstrated versus placebo after year 1 and after year 2 (>60%;  $p < 0.004$ ). No significant difference was demonstrated between the 3 active groups.

Safety was also very satisfying in all groups. Only one anaphylactic reaction occurred in the group treated with natural Bet v 1.

### Conclusions and next steps

- Bet v 1, as a major allergen, is as effective as the total birch pollen extract to desensitize.
- Recombinant Bet v 1 is as effective as purified natural Bet v 1 or birch pollen extract to desensitize.

“We are of course very satisfied to be the first allergen company to demonstrate the therapeutic effect of a recombinant major wild type allergen. On the basis of this study, we are undertaking a development program for a new tablet for sublingual desensitization : ORALAIR® Birch based on recombinant Bet V1 produced under the license agreement signed 3 years ago with BIOMAY, Vienna, Austria.” says Albert Saporta, Chairman & CEO of STALLERGENES.

## **About STALLERGENES**

*Stallergènes Group is today the world's leading pharmaceutical laboratory specialising in allergen immunotherapy, both in terms of number of patients treated (N°1) and sales (N°2). In its 40 years of existence, Stallergènes has established itself as a dynamic player, frequently as an innovator, in the battle to prevent and cure allergies, rhinitis and asthma in particular.*

*Stallergènes devotes over 15% of its sales to its Research and Development activities.*

*Stallergènes' development is focused on the French market and on international markets through its subsidiaries based in Germany, Spain, Italy, Portugal and Belgium, and its distributors based in Eastern Europe, North Africa and elsewhere.*

*Shares of the Group's parent company, Stallergènes SA, are listed on the Eurolist Compartment B of the Euronext Paris Stock Exchange.*

ISIN Code: FR0000065674

Reuters Code: GEN.PA

Bloomberg Code: GEN.FP

## **About BIOMAY**

*BIOMAY was the first company worldwide to succeed in producing a broad spectrum of the major allergens of grasses, trees and moulds by recombinant DNA technology.*

*BIOMAY intends to maintain this technological lead in the future through its extensive research resources, which includes over 40 high level scientists at two of Austrias leading university institutes.*

*BIOMAY produces and supplies recombinant allergens for research purposes.*



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### **Vos contacts**



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