

# Randomized, double-blind, placebo-controlled trial of standardized ragweed sublingual-liquid immunotherapy for allergic rhinoconjunctivitis.

Creticos PS1, Esch RE2, Couroux P3, Gentile D4, D'Angelo P5, Whitlow B2, Alexander M6, Coyne TC2.

## Abstract

### BACKGROUND:

Sublingual immunotherapy with liquid extracts provides an appealing alternative to subcutaneous immunotherapy for the treatment of allergic rhinoconjunctivitis (ARC), but a lack of robust evidence has deterred its use in North America.

### OBJECTIVE:

To determine the efficacy and tolerability of standardized glycerinated short ragweed sublingual allergen immunotherapy liquid (RW-SAIL) extract in subjects with ragweed-related ARC.

### METHODS:

This phase 3, randomized, placebo-controlled trial was conducted in North America. Subjects (age range, 18-55 years) with or without asthma were selected based on ARC symptom severity and erythema skin prick reaction to short ragweed. Subjects self-administered the maximum tolerated dose of RW-SAIL (n = 218) or placebo (n = 211) daily beginning approximately 8 to 16 weeks before and through the end of the ragweed pollen season. The primary end point was subject-assessed total combined daily rhinoconjunctivitis symptom and medication scores (TCS).

### RESULTS:

During the entire season, there was a 43% decrease in TCS in subjects treated with RW-SAIL compared with placebo. Similar decreases were observed in TCS between the 2 groups during peak season (42%) and in daily symptom scores during the entire (42%) and peak (41%) seasons. The occurrence of adverse events was similar between the treatment groups; most were mild in severity. Treatment-related oromucosal local application site reactions occurred early and were transient and self-limited. No anaphylaxis occurred.

### CONCLUSIONS:

This is the first successful North American confirmatory phase 3 clinical trial to demonstrate the safety and efficacy of a sublingual standardized ragweed allergen immunotherapy liquid extract for the treatment of ARC.