



MEETING ABSTRACT

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Efficacy and safety of MK-7243: a grass allergy sublingual immunotherapy tablet evaluated in Canadian adults and children

Jacques Hébert^{1*}, Michael Blaiss², Susan Waserman³, Harold Kim³, Peter Creticos⁴, Jennifer Maloney⁵, Amarjot Kaur⁵, Harold S Nelson⁶, Hendrik Nolte⁵

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Background

The effect of MK-7243 (2800 BAU/75,000 SQ [\sim 15 µg of *Phleum pratense p* 5], Merck/ALK-Abelló), a sublingual Timothy grass immunotherapy tablet, has been evaluated in several randomized, placebo-controlled, double-blind trials; three of these trials were conducted in adults and children in North America (the United States and Canada) who have allergic rhinitis with or without conjunctivitis (AR/C). We conducted a post-hoc analysis to investigate the effect of MK-7243 in Canadian subpopulations.

Methods

Data from Canadian subjects from the three trials were used in this investigation: P05238 (adults \geq 18 y; pollen season: 2009); P05239 (children 5– $<$ 18 y; pollen season=2009); and P08067 (adults \geq 65 y and children 5– $<$ 18 y; pollen season: 2012). Trial data from the same grass pollen seasons (GPS) were pooled. Subjects received once-daily MK-7243 or placebo starting \geq 12 wk before and continuing throughout the GPS, for a mean total of \geq 23 wk. The therapeutic effect of MK-7243 was evaluated for rhinoconjunctivitis symptoms and symptomatic medication use, measured as a total combined score (TCS=daily-symptom score [DSS; max=18]+daily-medication score [DMS; max=36]) averaged over the entire GPS. Safety was assessed by monitoring adverse events (AEs).

Results

Canadian subjects taking MK-7243 (n=42) in the pooled adult-pediatric 2009 trials showed a 38% mean TCS reduction versus placebo (n=54; -2.06 difference [95% CI: -3.72 , -0.39]; 3.32 vs. 5.37). Canadian subjects taking MK-7243 (n=122) in the adult-pediatric 2012 trial showed a 33% mean TCS reduction relative to placebo (n=122; -1.62 difference [95% CI: -2.54 , -0.71]; 3.34 vs. 4.96). Approximately 90% of treatment-related AEs were mild or moderate in severity. No serious or life-threatening treatment-related AEs occurred.

Conclusions

MK-7243 Timothy grass sublingual tablet significantly improved AR/C induced by Timothy grass pollen in Canadian adults and children 5 y and older. Similar efficacy and safety results were obtained for the overall populations of the three trials.

Trial registration

ClinicalTrials.gov Identifiers: NCT00562159; NCT00550550; NCT01385371.

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Authors' details

¹Centre de Recherche Appliquée en Allergie de Québec, Québec City, QC, Canada. ²Departments of Medicine and Pediatrics, University of Tennessee Health Science Center, Memphis, TN, USA. ³Department of Medicine, McMaster University, Hamilton, ON, Canada. ⁴Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA. ⁵Merck & Co.,

¹Centre de Recherche Appliquée en Allergie de Québec, Québec City, QC, Canada

Full list of author information is available at the end of the article

Inc., Whitehouse Station, NJ, USA. ⁶Departments of Medicine and Pediatrics,
National Jewish Health, Denver, CO, USA.

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