Mometasone Furoate Reduces Ocular Symptoms of Seasonal AR

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Abstract

Objectives: To demonstrate clinical efficacy in reducing the ocular symptoms of SAR using mometasone furoate nasal spray (MFNS).

Methods: A Phase III, double-blind, randomized, placebo-controlled, multicenter study compared MFNS 200 mcg QD, dosed in the morning (AM), for treatment of ocular symptoms associated with SAR. Subjects were at least 12 years old with at least a 2-year history of SAR. In daily diaries, subjects evaluated AM ocular symptom severity on a scale of 0 (none) to 3 (severe) on treatment Days 1 to 15. Corrimal endpoints included change from baseline in average AM ocular symptom scores (conjunctivitis, rhinorrhea, sneezing, and itching) and instantaneous AM total ocular symptom score (iTOSS) (sum of individual eye symptom scores for itching/burning, tearing/watering, and redness). Days 2 to 15.

Results: MFNS 200 mcg QD demonstrated statistically significant improvements in AM iTOSS compared with SAR. The first prospective results demonstrate that MFNS significantly reduces ocular symptoms in subjects with SAR.

Background

• Allergic rhinitis (AR) affects 10%–40% of the global population, or approximately 500 million people.1

• A majority of individuals with AR experience both nasal and ocular symptoms, such as tearing, itching, and redness (allergic conjunctivitis).2

• Intranasal corticosteroids (INSs) are the most efficacious medication available for AR.3

• Randomized, placebo-controlled clinical trials have demonstrated the efficacy and safety of INSs for the treatment of nasal and ocular symptoms associated with SAR.4,5

• Data from several retrospective analyses have shown statistically significant reductions in total nasal symptom score (TNSS) and total ocular symptom score (TOSS) in individuals with moderate-to-severe seasonal AR.5,6

Conclusions: MFNS 200 mcg QD demonstrated statistically significant improvements in AM iTOSS associated with SAR. These are the first prospective results demonstrating that MFNS significantly reduces ocular symptoms in subjects with SAR.

Methods

Study Design

• This was a Phase III, double-blind, randomized, multicenter, parallel-group study in subjects 12 years of age and older with SAR. The trial consisted of a 14-day screening period followed by a 15-day treatment period conducted in the spring.

• Qualified as SAR if randomized a 1:1 ratio to MFNS 200 mcg QD or placebo.

• Inclusion and exclusion criteria are given in Table 1.

Table 1. Major inclusion and exclusion criteria.

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tr>
<td>≥ 12-year documented history of SAR</td>
<td>History of anaphylaxis and/or other severe local reactions to skin testing</td>
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<td>Positive skin prick test response to an appropriate seasonal allergen</td>
<td>History of asthma neoeastalizing use of inhaled or systemic steroids</td>
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<td>Clinically symptomatic at baseline (i.e., ≥ 2 on any non-diary reflective [IPRO] scores for the 3 days prior to baseline)</td>
<td>Upper respiratory tract or sinus infection that required antibiotic therapy within at least a 14-day washout prior to the screening visit or a viral upper respiratory infection within 7 days prior to baseline visit</td>
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<tr>
<td>Positive skin prick test response to an appropriate seasonal allergen</td>
<td>Rhinitis medicamentosus</td>
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<tr>
<td>Clinically symptomatic at baseline (i.e., ≥ 2 on any non-diary reflective [IPRO] scores for the 3 days prior to baseline)</td>
<td>Allergies to more than two classes of medications</td>
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<tr>
<td>No history of ocular symptoms (itching/burning, tearing/watering, and redness)</td>
<td>Structural abnormalities that interfere with nasal air flow</td>
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• This is the first prospective study to show that MFNS significantly reduces ocular symptoms in subjects with SAR.

Statistical Analysis

• Statistical comparisons for efficacy were based on the comparison of MFNS versus placebo in the average AM change from baseline in the instantaneous scores over Days 2–15 at the two-sided alpha = 0.05.