**Evidence Table 13. Pharmacologic Therapy: Immunomodulators—Anti-Immunoglobulin E**

Abbreviations used in table:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>AE</td>
<td>adverse event</td>
</tr>
<tr>
<td>BDP</td>
<td>beclomethasone dipropionate</td>
</tr>
<tr>
<td>Der f</td>
<td><em>Dermatophagoides farinae</em></td>
</tr>
<tr>
<td>Der p</td>
<td><em>Dermatophagoides pteronyssinus</em></td>
</tr>
<tr>
<td>EAACI</td>
<td>European Academy of Allergology and Clinical Immunology</td>
</tr>
<tr>
<td>FEV₁</td>
<td>forced expiratory volume in 1 sec</td>
</tr>
<tr>
<td>HD</td>
<td>high dose</td>
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<tr>
<td>ICS</td>
<td>inhaled corticosteroid</td>
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<tr>
<td>IgE</td>
<td>immunoglobulin E</td>
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<tr>
<td>ITT</td>
<td>intent-to-treat</td>
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<tr>
<td>LABA</td>
<td>long-acting beta-agonist</td>
</tr>
<tr>
<td>NNT</td>
<td>number needed to treat</td>
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<tr>
<td>O</td>
<td>omalizumab</td>
</tr>
<tr>
<td>P</td>
<td>placebo</td>
</tr>
<tr>
<td>PD_{20}FEV₁</td>
<td>cumulative dose of methacholine producing a 20% decrease in FEV₁</td>
</tr>
<tr>
<td>PEF</td>
<td>peak expiratory flow</td>
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<tr>
<td>QoL</td>
<td>quality of life</td>
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<tr>
<td>SAE</td>
<td>severe adverse event</td>
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<tr>
<td>SD</td>
<td>standard deviation</td>
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<tr>
<td>SIT</td>
<td>specific immunotherapy</td>
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* indicates primary outcome
### Evidence Table 13. Pharmacologic Therapy: Immunomodulators—Anti-Immunoglobulin E

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<tr>
<th>Citation (Sponsor)</th>
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<th>Purpose/Objective</th>
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<th>Asthma Severity at Baseline (If Reported)</th>
<th>Treatment</th>
<th>Dose</th>
<th>Duration of Active Treatment; Duration of Postintervention/Off Treatment Followup</th>
<th>Taper/Decrease Steroids</th>
<th>Lung Function</th>
<th>Exacerbations/Symptoms</th>
<th>Other</th>
</tr>
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</table>
| Boulet et al. | Multicenter, randomized, double-blind, parallel-group, placebo-controlled trial | To document safety and tolerance of rhuMAb-E25 and determine if it reduces the early asthmatic response of inhaled aeroallergens | 20 (19—1 withdrawal from treatment group) | Age 21–44 yr, mean = 27.4 yr (SD=8.1)  
Gender: 12 male, 8 female  
Ethnicity: Not reported  
Highly positive allergy skin-prick test to at least 1 common aeroallergen  
Highly positive history of asthma  
Highly positive history of emergency asthma treatment in past year, and FEV1 <65% pred. were predictive of greater probability of response. | Stable, mild allergic asthma requiring only an inhaled beta-agonist on demand  
FEV1 % pred. mean = 91.9 (SD=11.07)  
Arm 1: rhuMAb-E25 (0.4 mL/kg on day 0; 0.2 mL/kg on days 7, 14, 21, 28, 42, 56, and 70)  
Arm 2: Placebo (2.0 mg/kg IV)  
1 week off-treatment followup | 0.4 mL/kg on day 0; 0.2 mL/kg on days 7, 14, 21, 28, 42, 56, and 70 (2.0 mg/kg IV)  
9 weeks treatment, 1 week followup | 0 weeks treatment, 1 week off-treatment followup | 
18.8% vs. 33% to 34% (p=0.01) during early phase and from 24% to 9% vs. 23% to 18% during late response (p=0.047) | Mean serum-free IgE decreased 89% after rhuMAb-E25 (p<0.001); no change occurred in placebo group.  
Allergen PC20 improved significantly after rhuMAb-E25 but not after placebo (p<0.002).  
Trend was in favor of omalizumab for difference in FEV1.  
RhuMAb-E25 significantly attenuated both early- and late-phase responses to inhaled allergen challenge with allergen; reduced mean FEV1 from 20% to 18.8% vs. 33% to 34% (p=0.01) during early phase and from 24% to 9% vs. 23% to 18% during late response (p=0.047) | *Safety: 1 withdrawal after first dose, probably related to study drug  
*High BDP dose (>800 mcg/day), history of emergency asthma treatment in past year, and FEV1 <65% pred. were predictive of greater probability of response. |
| Fahy et al. | Double-blind, placebo-controlled, randomized parallel-group study | To examine the effects of neutralizing IgE on allergic airway responses | 19 (18) | Age Mean = 31.5 yr  
Total serum IgE, mean = 142 IU/L  
Mild asthma requiring only inhaled beta-2 agonists  
Arm 1: rhuMAb-E25 (n=10; 1 withdrawal)  
Arm 2: Placebo (n=9)  
5 mg/mL by 5-min IV  
150 mM NaCl, 10 mM acetate, pH 5.2 by 5-min IV  
8 weeks treatment, 1 week followup | 5 mg/mL by 5-min IV  
(0.1 mL/kg)  
150 mM NaCl, 10 mM acetate, pH 5.2 by 5-min IV | 9 weeks treatment, 1 week followup | 0 weeks treatment, 1 week off-treatment followup | 
*Trend was in favor of omalizumab for difference in FEV1.  
RhuMAb-E25 significantly attenuated both early- and late-phase responses to inhaled allergen challenge with allergen; reduced mean FEV1 from 20% to 18.8% vs. 33% to 34% (p=0.01) during early phase and from 24% to 9% vs. 23% to 18% during late response (p=0.047) | PC20 for methacholine improved, but not significantly.  
Free IgE concentrations in serum decreased significantly in rhuMAb-E25 group as compared to placebo group (p<0.001). | 1 subject was withdrawn from rhuMAb-E25 treatment at 4 weeks because of asthma exacerbation. |
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<th>Exacerbations Symptoms</th>
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<tr>
<td>Milgrom et al. Treatment of allergic asthma with monoclonal anti-IgE antibody. N Engl J Med 1999;341(26):1973–1983. (Genentech Inc.)</td>
<td>Multicenter, randomized, double-blind, placebo-controlled trial</td>
<td>To examine the efficacy of rhuMAb E25 as a treatment for allergic asthma</td>
<td>525 (261, 53 dropouts)</td>
<td>Age 12–74 yr, mean = 39.2 yr</td>
<td>Severe allergic asthma requiring daily ICS</td>
<td>Arm 1 Omalizumab (n=268; 19 withdrawals)</td>
<td>0.016 mg/kg IgE (IULM) every 4 weeks for 16 weeks; approximately 20% reduction every 2 weeks for weeks 16–28</td>
<td>Rescue astutoen, maximum of 8 puffs/day was allowed</td>
<td>28 weeks (16-week stable phase, 12-week reduction phase)</td>
<td>Median reduction in ICS dose was greater in omalizumab group (73% vs. 50%, p=0.001), 50% reduction in BDP dose for 72.4% of omalizumab group vs. 54.9% of placebo group (p=0.001). BDP was discontinued in 39.6% of omalizumab and 19.1% of placebo group (p=0.001).</td>
<td>Other (0.66) vs. 0.001)</td>
<td>50% HD (p=0.01) and 28% LD groups (p=0.01) vs. placebo group 44% of placebo group</td>
<td>3 HD, 3 LD, and 8 placebo subjects withdrew due to AE.</td>
</tr>
<tr>
<td>Busse et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. Am J Respir Crit Care Med 2001;163(2):184–190. (Novartis Pharmaceuticals Corp. and Genentech, Inc.)</td>
<td>Multicenter, double-blind, placebo-controlled, randomized Phase III trial</td>
<td>To assess the efficacy and tolerability of subcutaneous omalizumab in adolescents and adults with severe allergic asthma whose disease was not adequately controlled with ICS</td>
<td>108 (2): 184 Clin Immunol</td>
<td>Age 11–50 yr, mean = 30 yr (54 adolescents)</td>
<td>Moderately to severe perennial allergic asthma</td>
<td>Arm 1 High dose (HD) rhuMAb-E25 (n=106; 103+4 weeks)</td>
<td>5.8 mg/kg IgE/mL, 2.5 mg/kg IgE/mL</td>
<td>20 weeks: 12 weeks of continued ICS and half dose of treatment on days 0 and 4, full dose on day 7 and then once every 2 weeks. For 8 weeks, treatment continued and ICS was tapered. 10 weeks of followup.</td>
<td>After 12 weeks, all patients used reduced by 1.8 puffs/day in HD group (p=0.02) and by 1.2 puffs/day in LD group (p=0.24) vs. 0.8 puffs/day in placebo group. Decreases were maintained at 20 weeks.</td>
<td>PEF* favored treatment at all points (p&lt;0.01); FEV1% pred. was significantly higher for treatment group between weeks 4 and 12 and between weeks 18 and 28. Morning PEF increased 30.7 L/min in HD group (p=0.017) and 16.6 L/min in LD group vs. 11.3 L/min in placebo group. At 20 weeks, increase from baseline was 29.5 L/min in HD group (p=0.02), 20.6 L/min LD group (p=0.046), and 10.2 L/min in placebo group.</td>
<td>30–60% HD (p=0.03) and 28% LD groups (p=0.01) vs. placebo group. 44% of placebo group.</td>
<td>*Asthma symptom score at 12 weeks: 2.8 for HD group and 2.8 for LD group vs 3.3 for placebo group (p=0.008 and p=0.005, respectively)</td>
<td>3 HD, 3 LD, and 8 placebo subjects withdrew due to AE.</td>
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Study Design
Randomized, double-blind, placebo-controlled, parallel-group design

Study N (Number Evaluated)
304

Population Characteristics
Female 69.2%, male 30.8%

Asthma Severity at Baseline (If Reported)
Moderate-to-severe allergic asthma

Dose
0.016 mg/kg IU IgE/mL

Outcome Measures
Duration of active treatment: Duration of PDEF/FEV1/TDY

Taper/Decrease Steroids
Proportion able to reduce dose vs. P

40% of O vs. P group; change from baseline 0 in O group and 0.46 in P group (p=0.004).

Other
No treatment-related SAE occurred.


Study Design
Multicenter, randomized, double-blind, placebo-controlled, parallel-group study

Study N (Number Evaluated)
546

Population Characteristics
Female 51%, Ethnicity Not reported

Asthma Severity at Baseline (If Reported)
Moderate-to-severe allergic asthma

Dose
0.016 mg/kg IU IgE/mL every 4 weeks

Outcome Measures
Proportion able to reduce dose vs. P

58% of O vs. P group (p<0.001) and 52% fewer exacerbations per patient vs. placebo group.

Other
Suspected drug-related AE events for 1.1% of omalizumab group; none were serious.

Novartis Pharmaceuticals Corp.

Randoized, dual-blind, placebo-controlled trial (blinded treatment group reported here).

To evaluate the long-term effects of the anti-IgE antibody omalizumab in children with asthma treated for full 52 weeks.

225

(225)

Age 5–12 yr; mean = 9.4

Gender 70% male, 30% female

Ethnicity 75% Caucasian, 17% black, 8% other

Total serum IgE: range, 30–1,300 IU/mL (mean = 348); body weight: 25 kg

18% hospitalized for asthma in past year

204 moderate (FEV₁, % pred. >60%), 21 severe (FEV₁ <30% pred.)

Duration: range, 1–12 yr; mean = 6.1 yr

Asthma well controlled 23 months with ICS doses equivalent to 168–420 mcg/day of BDP

202 moderate (FEV₁, % pred. >60%), 21 severe (FEV₁ <30% pred.)

Duration: range, 1–12 yr; mean = 6.1 yr

Asthma well controlled 23 months with ICS doses equivalent to 168–420 mcg/day of BDP

17% hospitalized for asthma in past year

Omalizumab (n=225)

(1.5 mg/kg/IgE/mL per 4 weeks)

28-week treatment, 24-week open label extension, 12 weeks off study drug.

PEF, remaining stable

81% did not require other medication.

No change occurred in mean BDP dosage for anti-omalizumab antibodies were detected, no clinically significant changes observed in vital signs.

Log methacholine PC20 was significant (p =0.03) after treatment (change of 0.9 doubling doses); no change was found after placebo.


Novartis Pharma AG; Genentech, Inc.

Pooled analysis of 3 multicenter, randomized, double-blind, placebo-controlled trials

To investigate the effect of omalizumab (Omalizumab) as a recombinant humanized monoclonal anti-IgE antibody, on the rates of serious exacerbations during long-term therapy

1,465

(1,465)

Age ≥5 yr (2 studies, n=1,071); Ages 6–12 yr (1 study, n=394)

Gender Not reported

Ethnicity Not reported

Moderate-to-severe asthma

Duration of asthma: 2 yr

Total serum IgE: range, 30–700 IU/mL ( Adolescents/adults) or 30–1,300 IU/mL (children)

Required daily ICSs

Positive skin prick test to dust mite, cockroach, dog, or cat

Omalizumab (n=1,071)

Total serum IgE: range, 30–700 IU/mL ( Adolescents/adults) or 30–1,300 IU/mL (children)

Required daily ICSs

Positive skin prick test to dust mite, cockroach, dog, or cat

12 months. Dosages of BDP were stable over initial 16 weeks (steroid phase) and reduced over 9 weeks (25% every 2 weeks) with asthma control maintained for 4 weeks (steroid reduction phase). Minimum effective dose was maintained for 24 weeks (extension phase).

PEF, remaining stable

81% did not require other medication.

No change occurred in mean BDP dosage for anti-omalizumab antibodies were detected, no clinically significant changes observed in vital signs.

Log methacholine PC20 was significant (p =0.03) after treatment (change of 0.9 doubling doses); no change was found after placebo.

*Adverse events: 33% experienced AE, unrelated to drug; 0.7% AE was suspected as related to drug (1 AE resolved in 20 minutes).

*Incidence rate of ED treatment for asthma was lower for O vs. P group (21.3 vs. 3.48, p<0.01).

*Incidence rate of exacerbation was lower for O vs. P group (1.5 vs. 3.30 per 100 patient-years; RR 0.47, 95% CI 0.24 to 0.91, p=0.049).

*Incidence rate of asthma-related hospitalizations was lower in O vs. P group (0.26 vs. 0.42 per 100 patient-years; RR 0.60, 95% CI 0.25 to 0.99, p=0.049).
<table>
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<th>Study Design</th>
<th>Purpose/ Objective</th>
<th>Study N (Number Evaluable)</th>
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<th>Asthma Severity at Baseline (If Reported)</th>
<th>Treatment</th>
<th>Dose</th>
<th>Duration of Active Treatment; Duration of Followup</th>
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<th>Lung Function</th>
<th>Exacerbations/Symptoms</th>
<th>Other</th>
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<tr>
<td>Ayes et al. Efficacy and tolerability of anti-immunoglobulin E therapy with omalizumab in patients with poorly controlled (moderate-to-severe) allergic asthma. Allergy 2004;59(7): 761–768.</td>
<td>Multicenter, randomized, open-label, parallel-group study 6 centers in 5 European countries To investigate the efficacy and tolerability of omalizumab in patients with poorly controlled allergic asthma in an open-label study in which omalizumab was added to and compared against best standard care (BSC) as defined by the NHLBI.</td>
<td>312 (ITT analyses)</td>
<td>Age 12–73 yr; median 38 yr Gender 29% male, 71% female Ethnicity not reported Serum IgE: range, 27–886 IU/mL; median, 167 IU/mL (treatment group only) Poorly controlled, moderate-to-severe allergic asthma; receiving treatment at stages 3 and 4 of NHLBI guidelines 76% receiving LABA 91% with at least 1 emergency room visit in previous year FEV1 % pred.: range, 15–136; median = 71 Mean Wasserfallen asthma symptom score = 17.3</td>
<td>Arm 1 placebo</td>
<td>0.016 mg/kg/IgE (IU/mL) per 4 weeks Rescue salbutamol was permitted throughout the study.</td>
<td>52 weeks</td>
<td>Patients treated with omalizumab (n=173) reduced mean daily dose of ICS (Δ–342 mcg/day), and those with BSC alone showed slight increase (Δ+69 mcg/day), p&lt;0.001. Significant difference in FEV1 of 2.48 L for omalizumab vs. 2.28 L for BSC alone, p&lt;0.02.</td>
<td><strong>Those treated with omalizumab-experienced 4.64 fewer asthma deterioration-related incidents (ADRI) vs. those treated with BSC alone (49.6% reduction; 36.1% vs. 20.2%, respectively, remained ADRI-free during the study. Median time to first ADRI was 126 vs. 75 days, respectively (p&lt;0.001). Lower annualized mean number of exacerbations with occurred with omalizumab than BSC alone (1.12 vs. 2.26, p&lt;0.001). 49.5% omalizumab subjects vs. 24.4% BSC only were exacerbation free (p&lt;0.001).</strong> Percentages of AE were not significantly different between groups (p=0.116). 48 patients (16.5% of omalizumab group and 13.2% of BSC group) experienced SAE during the study.</td>
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<tr>
<td>Bousquet et al. Predicting response to omalizumab, an anti-IgE antibody, in patients with allergic asthma. Chest 2004;125(4): 1378–1386. (Novartis Pharma AG and Genentech, Inc.)</td>
<td>Multicenter, double-blind, randomized, placebo-controlled Phase III study Combined data from Bousquet et al. (2001) and Soler et al. (2001) To determine baseline characteristics predictive of best response to omalizumab therapy for allergic asthma, time to onset of response, and how long patients need to be treated before a response could be accurately predicted</td>
<td>1,070 (1,070)</td>
<td>Age 12–76 yr; mean = 49.4 yr Gender 43% male, 57% female Ethnicity Not reported Total serum IgE, 30–480 IU/mL (mean = 197); 41% with history of emergency asthma treatment in past year Symptomatic allergic asthma with daily doses of BDP (200–2,000 mcg/day; mean = 725 mcg/day). Duration 1–68 yr, mean = 24.8 yr; FEV1 % pred., mean = 69, 21.5% with FEV1 ≤75%</td>
<td>Arm 1 placebo</td>
<td>0.016 mg/kg/IgE (IU/mL) per 4 weeks Rescue salbutamol was permitted before a response occurred.</td>
<td>36 weeks</td>
<td>Significant improvements in FEV1 in the treatment group compared to placebo group were maintained for the entire study (in values ranged from &lt;0.001 to 0.019).</td>
<td>Time to exacerbation was longer for omalizumab patients (p&lt;0.001). Probability of exacerbation by week 16 was 20% for placebo subjects and 16% for omalizumab subjects.</td>
<td>Odds of being responder were 2.25 times higher (99% CI, 1.68 to 3.01) with omalizumab than with placebo. 61% of responders at 16 weeks had responded at 4 weeks and 87% had responded by 12 weeks.</td>
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<td>Djukanovic et al. Effects of treatment with anti-immunoglobulin E antibody omalizumab on airway inflammation in allergic asthma. Am J Respir Crit Care Med 2004; 170(6): 583–593.</td>
<td>Multicenter, randomized, double-blind, placebo-controlled, parallel-group design (5 centers)</td>
<td>To determine whether omalizumab has anti-inflammatory effects in the airways of patients with allergic asthma.</td>
<td>45 (42)</td>
<td>Age 19–48 yr, median = 26 yr Gender 47% male, 53% female Ethnicity Not reported</td>
<td>Stable asthma: 30 (66.7%) with mild asthma, 15 (33.3%) with moderately severe asthma Duration &gt;1 yr Treatment with inhaled beta-agonists only No acute exacerbations for at least 6 weeks Positive skin prick test for at least 1 of the following allergens: house dust mite, cockroach, dog, or cat PC wheal value, ≤8 mg/mL Sputum eosinophilia &gt;2% or more of total nonsquamous cells</td>
<td>Arm 1 Omalizumab (O) (n=22; n=21 completers) Arm 2 Placebo (P) (n=23; n=22 completers)</td>
<td>150–300 mg every 4 weeks or 225–375 mg every 2 weeks on the basis of concentration of serum total IgE and body weight at baseline</td>
<td>16 weeks after run-in period of 3 weeks</td>
<td>No difference in change in airway responsiveness (p=0.198) between groups. In O group, PCFEV1 changed from 1.01 to 0.73 mg/mL (p=0.47); in P group PCFEV1 changed from 0.54 to 0.87 (p=0.26).</td>
<td>*Mean percent of eosinophils in induced sputum decreased from 6.8% to 1.7% for O group (p&lt;0.001) and from 8.5% to 7.0% for P group (p=0.05). Difference in change between groups was +4.6% (p=0.05). Between-group differences for O vs. P for were: eosinophils in submucosa (p=0.03), IgE cells in epithelium (p=0.01) and submucosa (p&lt;0.001), CD4+ (p&lt;0.01), CD8+ (p&lt;0.001), CD19 (p&lt;0.05); T lymphocytes and B lymphocytes (p&lt;0.02).</td>
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<tr>
<td>Holgate et al. Efficacy and safety of a recombinant anti-immunoglobulin E antibody (omalizumab) in severe allergic asthma. Clin Exp Allergy 2004; 34(4): 632–638. Novartis Pharma AG and Genentech Inc.)</td>
<td>Multicenter, randomized, double-blind, placebo-controlled trial</td>
<td>To evaluate the ability of omalizumab to improve disease control to enable ICS reduction in patients with severe allergic asthma.</td>
<td>248 (22 dropouts; ITT analysis)</td>
<td>Age 12–75 yr, median = 40.8 yr Gender 39% male, 61% female Ethnicity Not reported Total serum IgE, 20–700 IU/mL</td>
<td>Severe asthma requiring &lt;1,000 mcg/day fluticasone for symptom control and positive SPTs to aeroallergens/eosinophils’ FEV1 %pred., mean = 64</td>
<td>Arm 1 Omalizumab (n=126, 115 completed) Arm 2 Placebo (n=120, 109 completed)</td>
<td>0/10 mcg/kg/3L (IU/mL) every 4 weeks Beta-agonists were allowed as needed</td>
<td>32 weeks, after 6- to 10-week run-in period followed by 16-week corticosteroid-reduction phase</td>
<td>*Patients receiving omalizumab had greater mean reduction in FEV1 compared to those receiving placebo: 37.2% vs. 43.3% (p=0.003), with 73.8% vs. 50.8% achieving ≥50% dose reduction (p=0.001). Median reduction in prednisone was 50% in high dose (p=0.046) and 60% in low dose (p=0.1) groups vs. 0% in placebo. 21.4% vs. 15.0% with 100% reduction (p=0.198). Trend in favor of omalizumab for FEV1 throughout; trend was significant at weeks 4, 20, 28, and 30.</td>
<td>*Difference in reduction of exacerbation rates did not reach statistical significance. 58% of omalizumab vs. 38% of placebo patients had improvement in asthma-related QoL (p&lt;0.01). 1 omalizumab and 5 placebo patients had SAE not considered drug related. Completer rates were 91.3% for omalizumab and 89.8% for placebo group.</td>
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<td>Vignola et al.</td>
<td>Multicenter, randomized, double-blind, placebo-controlled, parallel group trial</td>
<td>To evaluate the efficacy and safety of omalizumab in patients with concomitant allergic asthma and persistent allergic rhinitis</td>
<td>235 (n=196; Arm 1=95, Arm 2=101)</td>
<td>Moderate-to-severe allergic asthma: Duration ≥ 2 yr; FEV1 % pred., mean ± 1 SD: range, 41–108</td>
<td>Omalizumab (O) (n=209; Arm 2)</td>
<td>Subcutaneous administration of at least 0.15 mg/kg IgE every 4 weeks</td>
<td>16 weeks after 4-week run-in</td>
<td>Stable dose of BMD 500–1,200 mcg/day</td>
<td>No change in either group.</td>
<td>FEV1 (% predicted, mean = 78.4)</td>
<td>Area of wheal reaction decreased in O vs. P subjects (p &lt;0.01), but no difference after discontinuation of therapy.</td>
<td>IL-13 levels decreased (p=0.05)</td>
<td>NSAIDs, SAEs, and sICAM levels.</td>
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To evaluate the effect of add-on omalizumab on asthma exacerbations in patients with severe persistent asthma who were inadequately controlled despite GINA step 4 therapy

**Purpose/Objective**

To summarize asthma-related QoL outcomes associated with omalizumab treatment in moderate-to-severe allergic asthma

**Population Characteristics**

- Moderate-to-severe allergic asthma (3 trials with adult and adolescent patients), allergic asthma (1 trial with n=334 children and adolescents), and asthma and allergic rhinitis (1 trial with adult and adolescent patients)

**Data**

- All receiving ICS plus LABA
- 67% at high risk for asthma mortality

**Results**

- Difference in rescue medication use was not significant.

**Other**

- Change from baseline in mean morning PEFR was greater for omalizumab than placebo (p=0.042; rate ratio 0.738) after adjusting for baseline differences in history (NNT=2).

- Baseline asthma mortality mortality rate was lower in omalizumab vs. placebo (0.24 vs. 0.48; p=0.002; NNT=2).

- Mean change in symptom score was greater with omalizumab vs. placebo (p=0.039).

**Citation (Sponsor)**

- 316.
- Ann Allergy - 316 – 326.