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Original article

Safety and tolerability of omalizumab in children with allergic (IgE-mediated) asthma

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Tel.: +1 303-398-1999; Fax: +1 303-281-2189; milgromh@njhealth.org**Key words:**

Asthma – IgE – Omalizumab – Pediatric – Safety – Tolerability

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Citation: Curr Med Res Opin 2011; 27:163–69**Abstract****Objective:**

This pooled analysis assessed the safety of omalizumab in children with allergic (immunoglobulin E-mediated) asthma.

Study design:

Two double-blind, placebo-controlled studies in children (6 to < 12 years) with moderate-to-severe allergic asthma investigated the efficacy/safety of omalizumab. Children on optimized asthma care (inhaled corticosteroids ± other controller medications) were randomized (2:1) to omalizumab (75–375 mg sc, q2 or q4wk) or placebo. Pooled safety findings from these trials are presented in this publication.

Results:The safety population included 926 children (omalizumab, $n = 624$; placebo, $n = 302$). Adverse events (AEs) were more frequently reported in the placebo (91.7%) than omalizumab (89.7%) group. The most common AEs were nasopharyngitis, upper respiratory tract infection and headache. Suspected treatment-related AEs included headache, erythema and urticaria; none of which were reported by $\geq 2\%$ of patients receiving omalizumab. Serious AEs (SAEs) were reported by 3.4% and 6.6% of patients receiving omalizumab and placebo, respectively; the most common were appendicitis, pneumonia and bronchitis; no deaths were reported.**Conclusions:**

Omalizumab has an acceptable safety profile, with a risk of AEs similar to placebo. This, combined with its efficacy profile, suggests that omalizumab may provide an additional asthma management option for children (6 to < 12 years) uncontrolled with current therapy that follows established guidelines.

Introduction

An estimated 32% of children in the USA and Europe have asthma-like symptoms (recurrent cough, wheeze or breathlessness). Of these, 24% have weekly symptoms despite treatment with antibiotics, inhaled β_2 -agonists, inhaled corticosteroids (ICS), oral corticosteroids (OCS), oral anti-histamines, or cough and herbal medications¹. Asthma control falls short of guideline recommendations in large proportions of children with asthma worldwide². Although in many cases disease control can be improved by more intensive treatment, many children with asthma, particularly those with severe asthma, are poorly controlled despite receiving multiple controller medications³.

New treatment options for the control of symptoms of moderate-to-severe asthma in children could help to reduce the associated burden of morbidity and mortality. The risks and benefits of new therapies for use in a pediatric setting cannot be reliably established from studies conducted in adults⁴, and careful

analysis of safety outcomes is required when evaluating any new therapy for children.

Omalizumab is the first and only anti-immunoglobulin E (anti-IgE) antibody approved as an add-on therapy for the treatment of adults and adolescents (≥ 12 years of age) with moderate-to-severe (US) and severe (EU) allergic (immunoglobulin E [IgE] mediated) asthma^{5,6}. In the EU, the indication has recently been extended to include children (6 to <12 years) with severe allergic (IgE-mediated) asthma⁶. An extensive program of clinical trials has demonstrated a favorable efficacy and safety profile in adults and adolescents with allergic asthma^{7–15}.

The efficacy and safety of omalizumab have been investigated in two double-blind, placebo-controlled studies of 28 (Study 010) and 52 (Study IA05) weeks' duration in children (6 to <12 years old) with moderate-to-severe allergic asthma^{16,17}.

The objectives of this pooled analysis were to evaluate the safety profile of omalizumab in a large childhood population with moderate-to-severe persistent allergic asthma, and to supplement previously published data.

Methods

Both studies included in this pooled analysis were performed in accordance with the Declaration of Helsinki and its amendments. Institutional review boards or ethics committees at each centre approved the study. Written informed consent was provided by parents or legally acceptable guardians.

Study selection and designs

The study population in the present analysis consisted of patients (aged 6 to <12 years) who comprised the safety analyzable population from two large trials^{16,17}. In both studies children on optimized asthma care (ICS with or without other controller medications) were randomized to receive either subcutaneous omalizumab or placebo. Both studies have been described in detail previously^{16,17}. These two studies were selected for inclusion in this analysis as they were the only large-scale, randomized, double-blind, placebo-controlled studies of omalizumab in children (6 to <12 years) with persistent moderate-to-severe allergic (IgE-mediated) asthma.

Briefly, one study evaluated safety and efficacy in 628 patients aged 6 to <12 years with moderate-to-severe allergic (IgE-mediated) asthma inadequately controlled despite treatment with medium- or high-dose ICS, with or without other controller medications. Patients were randomized 2:1 to receive omalizumab (75–375 mg every 4 [q4wk] or 2 weeks [q2wk]) or placebo over 52 weeks (comprising a 24-week fixed-steroid phase followed by a 28-week adjustable-steroid phase)¹⁷.

The second study evaluated safety and efficacy in 298 patients aged 6–12 years* with moderate-to-severe allergic asthma, which was well controlled with ICS (168–420 $\mu\text{g}/\text{day}$ beclomethasone dipropionate or equivalent) and bronchodilator therapy as needed. Patients were randomized 2:1 to receive omalizumab (150–375 mg q4wk or q2wk) or placebo over 28 weeks (16-week steroid-stable phase, followed by an 8-week steroid-reduction phase [during which ICS was reduced to the minimum effective dose] and a second 4-week steroid-stable phase [during which the minimum effective dose was maintained])¹⁶.

The safety analyzable population included patients who had received at least one dose of study medication and provided any post-randomization data.

Exposure

Exposure to study medication was defined as the period between the first study drug administration date to the last visit date, or until the last dose date if patients did not complete the study on treatment.

Safety analyses

This pooled evaluation analyzed the safety of omalizumab in children aged 6 to <12 years with allergic asthma; therefore 12-year-old children enrolled in this study were excluded. AE data were collected and described by severity grade (mild, moderate, severe), and the assessed relationship to the study drug. Actions taken and outcomes were also recorded. An AE was defined as any undesirable sign, symptom or medical condition occurring after patients started study drug, even if the event was not considered to be related to the study drug. Serious AEs (SAEs) were defined as events which were fatal or life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability or incapacity, constituted a congenital anomaly or a birth defect, or required medical or surgical intervention. AEs were coded according to version 11.0 of the Medical Dictionary for Regulatory Affairs. Frequency of AEs was reported as numbers and percentages of patients experiencing an AE in each treatment group. No inferential statistical analyses were performed.

AEs of special interest

The safety analyzable population data from the pediatric clinical program was searched for various AEs of interest. Hypersensitivity and AEs suggestive of hypersensitivity (skin rash, urticaria, or serum sickness syndrome) were

*This pooled evaluation analyzed the safety of omalizumab in children aged 6 to <12 years with allergic asthma; therefore twelve-year-old children enrolled in this study were excluded.

recorded. Serum sickness was reported either using the preferred term 'serum sickness' or using a defined cluster of AEs potentially related to serum sickness (Table 1), regardless of temporal relationship. Occurrences of anaphylaxis, either reported using the preferred term 'anaphylaxis' or using a defined cluster of AEs according to the Sampson criteria for diagnosis of anaphylaxis (regardless of temporal relationship)¹⁸, were recorded. Cases of malignant neoplasia, parasitic infection and Churg–Strauss syndrome were also recorded.

Laboratory data were also evaluated to identify possible hematological or biochemical shifts from normal to

clinically notable abnormal values outside the normal local laboratory range and:

- $\geq 20\%$ decrease from baseline for hemoglobin, hematocrit and neutrophils;
- $< 2.4 \times 10^9/L$ for white blood cell count;
- $\geq 3 \times$ upper limit of normal for alanine aminotransferase and aspartate aminotransferase;
- $> 133 \mu\text{mol/L}$ for creatinine;
- $< 75 \times 10^9/L$ or $\geq 50\%$ decrease from baseline for platelet count.

Results

Patient disposition, baseline characteristics and study drug exposure

In total, the safety population included 926 patients; 624 received omalizumab. The numbers of patients completing or withdrawing from the study, and reasons for withdrawal are summarized in Figure 1. Similar numbers of patients treated with omalizumab and placebo completed the studies (86.9% versus 86.4%). The main reason for discontinuation in the omalizumab group was withdrawal of consent (4.3%). There were three (0.5%) AE discontinuations in the omalizumab group and one (0.3%) AE discontinuation in the placebo group (see below).

The baseline demographic and asthma-related disease characteristics of patients were similar in omalizumab and placebo treatment groups (Table 2). The majority of patients were Caucasian (64 versus 68%), male (69 versus 67%) and aged 6–9 years (58 versus 64%) in the omalizumab and placebo of which groups, respectively.

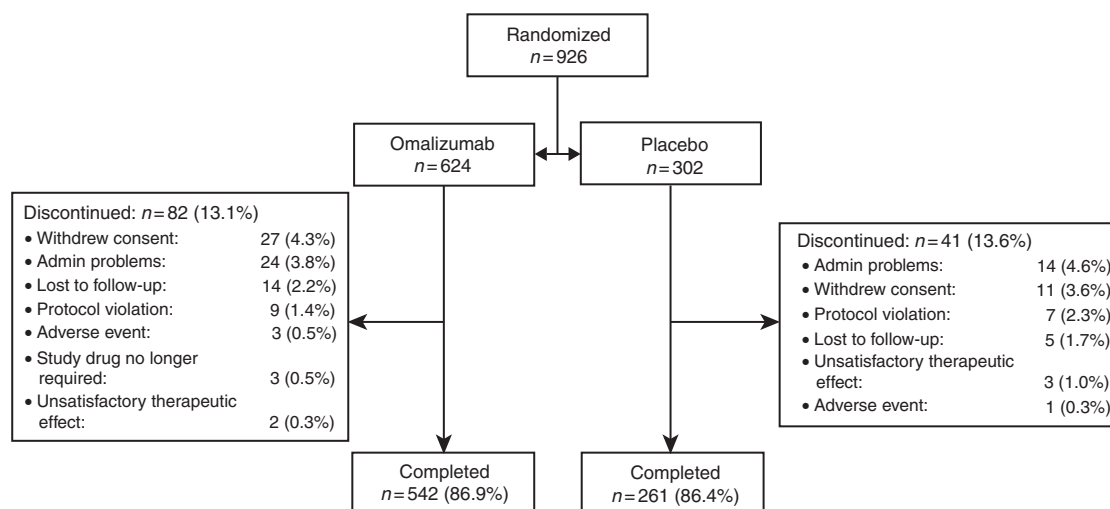
Table 1. AEs of special interest*.

	Omalizumab [‡] (n = 624)	Placebo (n = 302)
Skin rash	42 (6.7)	26 (8.6)
Rash	21 (3.4)	13 (4.3)
Hypersensitivity reactions	39 (6.3)	21 (7.0)
Bleeding-related disorders	26 (4.2)	13 (4.3)
Epistaxis	21 (3.4)	10 (3.3)
Serum sickness syndrome [†]	25 (4.0)	9 (3.0)
Urticaria	22 (3.5)	11 (3.6)
Anaphylaxis (as reported)	1 (0.2)	1 (0.3)
Anaphylaxis (Sampson criteria)	1 (0.2)	0

*Only preferred terms $\geq 3\%$ in any group are included (excluding anaphylaxis).

[†]Patients with at least one event in Category A (angioneurotic edema, angioedema, dermatitis contact, dermatitis allergic, pruritus, pruritus generalized, toxic skin eruptions, any preferred term including rash, any preferred term including urticaria) and one in Category B (pyrexia, arthralgia, influenza-like illness, influenza, malaise, lymphadenopathy, lymphadenitis, lymph node pain, myalgia).

[‡]The dose of omalizumab was determined by the omalizumab dosing tables (75 – 375 mg by subcutaneous (sc) injection, every 4 (q4wk) or 2 weeks (q2wk)).



One IA05 patient who received study medication (placebo) without being randomized is included as a discontinued patient.

Figure 1. Patient disposition.

Table 2. Baseline demographic and clinical characteristics.

	Omalizumab§ (n = 624)	Placebo (n = 302)
Age, years		
Mean (SD)	8.8 (1.70)	8.6 (1.68)
Age group, n (%)		
6–9 years*	360 (57.7)	192 (63.6)
10–11 years	264 (42.3)	110 (36.4)
Sex, n (%)		
Male	430 (68.9)	201 (66.6)
Female	194 (31.1)	101 (33.4)
Race, n (%)		
Caucasian	398 (63.8)	204 (67.5)
Black/other	226 (36.2)	98 (32.5)
Total IgE, IU/mL		
Mean (SD)	435.9 (323.24)	414.7 (323.97)
FEV ₁ % predicted, n (%)†		
<80%	230 (36.9)	98 (32.5)
≥80%	393 (63.0)	204 (67.5)
FEV ₁ % predicted		
Mean (SD)	85.2 (16.87)	86.6 (17.09)
Baseline ICS dose, µg/day‡		
Mean (SD)	403.9 (288.37)	399.4 (288.16)

*Includes one patient aged five in Study 010.

†Baseline forced expiratory volume in 1 second (FEV₁) was not recorded for one patient (IA05).

‡Fluticasone equivalent.

§The dose of omalizumab was determined by the omalizumab dosing tables (75–375 mg sc, q4wk or q2wk).

SD, standard deviation.

Baseline lung function, IgE levels and ICS dose were similar between groups.

Mean exposure was approximately 42 weeks, and over 90% of patients were exposed to omalizumab for ≥24 weeks. As the duration of Study 010 was 28 weeks, exposures of >28 weeks are from Study IA05.

Safety and tolerability

Distribution and severity of AEs

Overall, 89.7% and 91.7% of patients on omalizumab and placebo, respectively, experienced one or more AEs, most of which were of mild or moderate severity (90%). The most common AEs were nasopharyngitis, upper respiratory tract infection, headache and sinusitis (Table 3). Treatment-related AEs were reported by 6.6% and 5.0% of patients receiving omalizumab and placebo, respectively; the most common were headache, erythema and urticaria (omalizumab: 1.3%, 1.0%, 1.0%; placebo: 1.7%, 0.7%, 0.3%, respectively).

Three patients on omalizumab (0.5%) withdrew from a study due to AEs. These were urticaria (one patient), serious bronchitis (one patient) and non-serious headache (one patient). The cases of urticaria and non-serious headache were suspected to be related to study drug. One patient on placebo (0.3%) withdrew due to a diagnosis of medulloblastoma.

The overall frequency of AEs was higher during Weeks 12 to 28 of treatment than during Weeks 0 to 12

Table 3. Most common AEs (≥3% in any group).

Medical Dictionary for Regulatory Affairs organ class preferred term	Omalizumab‡ (n = 624)	Placebo (n = 302)
Infections and infestations, n (%)		
Nasopharyngitis	147 (23.6)	70 (23.2)
Upper respiratory tract infection	133 (21.3)	78 (25.8)
Sinusitis	101 (16.2)	57 (18.9)
Influenza	61 (9.8)	30 (9.9)
Bronchitis	42 (6.7)	31 (10.3)
Viral upper respiratory tract infection	42 (6.7)	34 (11.3)
Pharyngitis	41 (6.6)	21 (7.0)
Pharyngitis streptococcal	38 (6.1)	16 (5.3)
Otitis media	36 (5.8)	16 (5.3)
Ear infection	31 (5.0)	15 (5.0)
Viral infection	27 (4.3)	17 (5.6)
Rhinitis	25 (4.0)	20 (6.6)
Gastroenteritis	24 (3.8)	17 (5.6)
Gastroenteritis viral	24 (3.8)	7 (2.3)
Pneumonia	17 (2.7)	15 (5.0)
Acute sinusitis	12 (1.9)	9 (3.0)
Tonsillitis	8 (1.3)	14 (4.6)
Lower respiratory tract infection	6 (1.0)	10 (3.3)
Respiratory, thoracic and mediastinal disorders, n (%)		
Cough	71 (11.4)	40 (13.2)
Pharyngolaryngeal pain	63 (10.1)	31 (10.3)
Rhinitis allergic	41 (6.6)	21 (7.0)
Nasal congestion	32 (5.1)	16 (5.3)
Epistaxis	21 (3.4)	10 (3.3)
Gastrointestinal disorders, n (%)		
Vomiting	48 (7.7)	33 (10.9)
Abdominal pain upper	39 (6.3)	15 (5.0)
Abdominal pain	26 (4.2)	13 (4.3)
Diarrhea	25 (4.0)	15 (5.0)
Nausea	17 (2.7)	10 (3.3)
Nervous system disorders, n (%)		
Headache	129 (20.7)	59 (19.5)
General disorders and administration site conditions, n (%)		
Pyrexia	94 (15.1)	34 (11.3)
Skin and subcutaneous tissue disorders, n (%)		
Rash	21 (3.4)	13 (4.3)
Urticaria	19 (3.0)	10 (3.3)
Injury, poisoning, and procedural complications, n (%)		
Arthropod bite	20 (3.2)	2 (0.7)
Joint sprain	11 (1.8)	10 (3.3)
Musculoskeletal and connective tissue disorders, n (%)		
Pain in extremity	12 (1.9)	9 (3.0)
Eye disorders, n (%)		
Conjunctivitis	10 (1.6)	11 (3.6)
Ear and labyrinth disorders, n (%)		
Ear pain	20 (3.2)	12 (4.0)

‡The dose of omalizumab was determined by the omalizumab dosing tables (75–375 mg sc, q4wk or q2wk).

and 28 to 52, but the frequency of all AEs and of individual AEs was generally similar between treatment groups.

Serious adverse events

SAEs were reported by 3.4% and 6.6% of patients receiving omalizumab and placebo respectively; the most common SAEs were appendicitis, pneumonia and bronchitis (omalizumab: 0.6%, 0.5%, 0.3%; placebo: 0.3%, 2.3%, 0.3%, respectively). The only SAE reported in the omalizumab group that was suspected to be related to study

drug was a moderate tic disorder. There were no deaths during the studies.

AEs of special interest

The frequency of AEs under the terms skin rash, hypersensitivity, bleeding disorders, serum sickness syndrome, urticaria and anaphylaxis is shown in Table 1. Skin rashes were predominantly mild and of similar prevalence between treatment groups (Table 1). Episodes of urticaria were mild or moderate, and seen in similar proportions of omalizumab and placebo-treated patients.

AEs compatible with hypersensitivity reactions occurred in 6.3% of patients in the omalizumab group and 7.0% of patients receiving placebo (Table 1). The most common event was allergic conjunctivitis. The percentage of patients experiencing bleeding-related AEs was similar between treatment groups (Table 1). None of these events was reported as severe. Epistaxis was the most frequently reported bleeding-related disorder by preferred term (3.4% and 3.3% of patients in the omalizumab and placebo groups, respectively).

There were no cases of serum sickness reported by the preferred term. The percentage of patients with clusters of terms potentially related to serum sickness syndrome was small, and similar between treatment groups (Table 1). Approximately 30% of patients in both treatment groups experienced individual AEs that could be considered possible components of serum sickness syndrome (based on a cluster of terms), the majority of which were mild. These AEs were reported with sufficient temporal delay not to be considered serum sickness syndrome. Three patients experienced severe AEs in the omalizumab group that could be considered to be components of serum sickness (one influenza-like illness, one influenza and one maculopapular rash). The most frequently reported AEs that could be considered a component of serum sickness were mild pyrexia and mild influenza.

One patient in each group had an episode of anaphylaxis, described as moderate in severity; neither was suspected to be related to study medication. One omalizumab patient presented with anaphylaxis subsequent to exposure to pethidine hydrochloride (Demerol) prescribed as a prophylactic pain medication, and one placebo patient experienced an anaphylactic reaction (swelling) attributed to ingestion of peanuts. One omalizumab patient also had AEs compatible with anaphylaxis according to Sampson criteria (face rash and shortness of breath)¹⁸ although these AEs were experienced with sufficient temporal delay (shortness of breath was reported 59 days after face rash) not to be considered an anaphylactic reaction.

One patient receiving placebo treatment reported a malignancy (medulloblastoma). No cases of Churg–Strauss syndrome or helminthic infection were reported.

Laboratory variables

Shifts from normal to clinically abnormal laboratory values were rare in omalizumab-treated patients and the percentage of patients experiencing notable changes was similar between treatment groups. The most frequently reported shifts by notable criteria were in neutrophils, the majority of which were to low values (13.1% and 12.6% of patients on omalizumab and placebo, respectively) (Table 4). Other shifts according to notable criteria occurred in $\leq 1\%$ of patients in any treatment group. There was no difference between treatment groups in the number of patients who experienced notably high or low systolic/diastolic blood pressures. Notably abnormal pulse rates were slightly more frequently high than low, but there was no difference between treatment groups.

Discussion

The present analysis comprised the pooled safety populations from both double-blind, placebo-controlled studies of omalizumab in pediatric allergic asthma (Study IA05 and Study 010). The population approached 1000 patients, a size large enough to detect common safety concerns. Overall, the findings are consistent with previously published data; omalizumab was generally well tolerated in children with allergic (IgE-mediated) asthma, and was associated with an overall frequency of AEs similar to that of placebo^{16,17}. The present analysis revealed no new or unexpected safety findings. The most frequent AEs were reported by a similar number of patients in each group, and the frequency of SAEs was lower in the omalizumab group compared with placebo. There were no deaths, and SAEs were uncommon. When considered alongside previously reported efficacy outcomes (including reduction in exacerbations and inhaled corticosteroids requirements)^{16,17}, the safety findings from this analysis indicate that omalizumab has a favorable benefit/risk profile in children with inadequately controlled, moderate-to-severe, allergic asthma.

Treatment-related AEs occurred in 6.6% and 5.0% of omalizumab- and placebo-treated patients, respectively, with no individual treatment-related event occurring in more than 2% of patients. AEs compatible with hypersensitivity reactions, serum sickness syndrome and anaphylaxis were generally uncommon, and no cases of malignancy, Churg–Strauss syndrome or helminthic infection were observed in patients receiving omalizumab.

Previous analysis of data from the omalizumab clinical development program in adults and adolescents revealed a slight numerical imbalance in malignancies between the omalizumab-treated group (25 cancers in 5015 patients; 0.5%) compared with the control group (five cancers in 2854 patients; 0.18%)¹⁹. However, a detailed analysis of clinical data, tumor characteristics and their relationship

Table 4. Shifts by notable criteria* in laboratory parameters.

	Omalizumab‡ (N= 624) n (%)	Placebo (N= 302) n (%)
Hematology		
Hematocrit (L/L)		
Normal or high at baseline by local lab range	598 (95.8)	292 (96.7)
Shifted to low by notable criteria	2 (0.3)	3 (1.0)
Hemoglobin (g/L)		
Normal or high at baseline by local lab range	597 (95.7)	288 (95.4)
Shifted to low by notable criteria	2 (0.3)	2 (0.7)
Neutrophils (10 ⁹ /L)		
Normal or high at baseline by local lab range	573 (91.8)	271 (89.7)
Shifted to low by notable criteria	82 (13.1)	38 (12.6)
Platelets (10 ⁹ /L)		
Normal or high at baseline by local lab range	621 (99.5)	300 (99.3)
Shifted to low by notable criteria	4 (0.6)	1 (0.3)
White blood cells (10 ⁹ /L)		
Normal or high at baseline by local lab range	598 (95.8)	295 (97.7)
Shifted to low by notable criteria	0	0
Clinical chemistry		
Alanine aminotransferase (U/L)		
Normal or low at baseline by local lab range	585 (93.8)	285 (94.4)
Shifted to high by local lab range	27 (4.3)	15 (5.0)
Shifted to high by notable criteria	2 (0.3)	2 (0.7)
Aspartate aminotransferase (U/L)		
Normal or low at baseline by local lab range	592 (94.9)	287 (95.0)
Shifted to high by local lab range	21 (3.4)	12 (4.0)
Shifted to high by notable criteria	1 (0.2)	1 (0.3)
Creatinine (μmol/L)		
Normal or low at baseline by local lab range	538 (86.2)	266 (88.1)
Shifted to high by local lab range	65 (10.4)	43 (14.2)
Shifted to high by notable criteria	0	0

*Notable criteria were hematocrit $\geq 20\%$ decrease from baseline; hemoglobin $\geq 20\%$ decrease from baseline; neutrophils $\geq 20\%$ decrease from baseline; platelet count $< 75 \times 10^9/L$ or $\geq 50\%$ decrease from baseline; white blood cell count $< 2.4 \times 10^9/L$; alanine aminotransferase, aspartate aminotransferase $\geq 3 \times ULN$; creatinine $> 133 \mu\text{mol/L}$ or values for any of these criteria outside the normal range.

‡The dose of omalizumab was determined by the omalizumab dosing tables (75–375 mg sc, q4wk or q2wk).

to omalizumab, together with a literature review, indicated that there was no causal link between omalizumab and cancer²⁰.

The low incidence of anaphylaxis in this analysis is consistent with that reported in a review of data from previous clinical trials in adults and adolescents²⁰. Although the risk of anaphylaxis appears low in patients receiving omalizumab, the onset of symptoms may be delayed and progression may be protracted²¹. This should be considered when administering omalizumab. Precautions should be taken that include availability of medications for the immediate treatment of an anaphylactic reaction and informing patients of the risks and need for prompt medical attention.

Although no evidence of an increased risk of cardiovascular or cerebrovascular events arose from the analyses in children presented in this publication, concern was raised by the US Food and Drug Administration regarding the incidence of cardiovascular AEs in adults and adolescents²². This was based on interim analyses of data from the EXCELS study that enrolled patients of 12 years of age

or older²³ indicating that there was an increased risk of cardiovascular and cerebrovascular events in patients receiving omalizumab. No causal relationship has been established between omalizumab and cardiovascular or cerebrovascular events. Further, the regulatory authorities have not recommended any changes to prescribing information and do not advise patients or healthcare professionals to stop omalizumab²². The EXCELS study is ongoing and may provide additional information on cardiovascular/cerebrovascular risk when analysis is complete.

A potential limitation to this study is that it is a retrospective analysis of two randomized controlled trials to assess the efficacy and safety of omalizumab in pediatric patients. The current analysis provides data from a total of 926 patients for a treatment duration of 52 weeks. Novartis will continue to prospectively monitor the safety of omalizumab in all patients, including pediatric patients, in the post-marketing setting.

There is a significant population of children whose allergic asthma is uncontrolled on current therapy³, and

there is debate regarding the safety of prolonged use of ICS²⁴, OCS²⁵ and long-acting β_2 -agonists²⁶. Previous studies have demonstrated the efficacy of add-on omalizumab at reducing clinically significant exacerbations in children with allergic (IgE-mediated) asthma.

To conclude, omalizumab has a unique mechanism of action that differs from the currently available therapies for the treatment of children with moderate-to-severe allergic asthma. The safety profile of omalizumab presented here suggests that omalizumab may provide an additional new management option for children (6 to <12 years) with inadequately controlled allergic (IgE-mediated) asthma despite current therapy that follows established guidelines.

Transparency

Declaration of funding

The study was sponsored by Novartis Pharma AG.

Declaration of financial/other relationships.

A.F., C.F.V. and S.J. have disclosed that they are employees of the study sponsor.

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