

Recombinant humanized mAb-E25, an anti-IgE mAb, in birch pollen-induced seasonal allergic rhinitis

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Background: Allergic rhinitis is a common condition often requiring treatment.

Objective: We evaluated whether recombinant humanized (rhu)mAb-E25, a recombinant humanized construct of a murine antibody that binds to circulating IgE, could control symptoms and reduce intake of concomitant medication in seasonal allergic rhinitis (SAR) induced by birch pollen if given subcutaneously in a dose schedule predicted to reduce serum free IgE levels below 25 ng/mL.

Methods: We randomly assigned 251 adult subjects with a history of SAR and a positive skin test response to birch pollen to receive 300 mg of rhuAb-E25 or placebo given 2 or 3 times during the season, depending on baseline IgE levels. The primary efficacy variable was the subject's average daily nasal symptom severity score (sneezing, itching, runny, and stuffy nose) from diary data collected over the double-blind treatment period. Secondary efficacy variables included the average number of rescue antihistamine tablets per day, the proportion of days with any SAR medication use, and rhinoconjunctivitis-specific quality of life (QOL).

Results: Significant between-treatment differences in favor of rhuAb-E25 were observed in average daily nasal symptom severity scores, the average number of tablets of rescue antihistamines per day, the proportion of days with any SAR medication use, and all domains of QOL. Serum-free IgE levels were markedly lower in rhuAb-E25-treated subjects and were associated with clinical effectiveness. Recombinant humanized mAb-E25 was well tolerated. No anti-rhuAb-E25 antibodies were detected.

Conclusion: Compared with placebo, rhuAb-E25 was safe and effective in controlling birch pollen-induced SAR symptoms, with less concomitant medication use and improved

QOL. This study shows the therapeutic potential of anti-IgE antibody in SAR. (*J Allergy Clin Immunol* 2000;106:253-9.)

Key words: Allergic rhinitis, allergy, IgE, anti-IgE, recombinant humanized mAb-E25

Allergic rhinitis is a common condition. Recent multinational surveys have found self-reported prevalence of up to 41%.¹⁻³ Epidemiologic data suggest that the prevalence of allergic diseases has risen over the last 10 to 20 years.³⁻⁵ The key feature of allergic disease is the production of allergen-specific IgE antibodies in sensitized individuals.⁶ Binding of allergens to antigen-binding sites of IgE on the surface of basophils and mast cells, with subsequent cross-linkage of IgE molecules and aggregation of high-affinity receptors for IgE (FcεRI), triggers the release of histamine, leukotrienes, and other inflammatory mediators.⁷ Currently available therapeutic strategies include antihistamines,⁸ corticosteroids,⁹ mast cell stabilizers,¹⁰ and immunotherapy for desensitization of specific allergens.¹¹ Removal of circulating IgE by directing mAbs to the Fc part of the IgE molecule that binds to FcεRI, thus inhibiting binding of IgE to its receptors and mediator release, represents a novel therapeutic approach in the treatment of allergic disease.

Recombinant humanized (rhu)mAb-E25 is a recombinant humanized construct of murine antibody MAE11 that binds to circulating IgE at the same site on the Fc portion of the IgE molecule as the high-affinity receptor FcεRI and possibly the low-affinity receptor FcεRII.^{12,13} Consequently, this type of anti-IgE antibody cannot bind to Fcε receptors or to receptor-bound IgE and thus cannot activate target cells.^{12,14}

The aim of this study was to determine whether subcutaneous doses of rhuAb-E25 would control the symptoms, reduce the use of rescue medication, and improve the quality of life (QOL) of patients with seasonal allergic rhinitis (SAR) induced by birch pollen, the most common cause of SAR in Northern Europe.¹⁵⁻¹⁸ We undertook a randomized, double-blind, placebo-controlled trial with two different dose schedules of rhuAb-E25 on the basis of baseline IgE levels. The dose and time schedules we used were predicted to reduce serum free IgE levels to below 25 ng/mL. On the basis of a previous study, this was considered important for optimal efficacy.¹⁹

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Abbreviations used

ANCOVA:	Analysis of covariance
CV:	Coefficient of variation
LSM:	Least-squares means
QOL:	Quality of life
rhumAb:	Recombinant humanized mAb
RQLQ:	Rhinoconjunctivitis-specific quality of life questionnaire
SAR:	Seasonal allergic rhinitis

METHODS**Study subjects**

Subjects were aged 17 to 66 years (53% female subjects), weighed 48 to 110 kg, and had the following: a positive skin prick test response to birch pollen extract (wheal of equal or larger size as that produced with 10 mg/mL histamine and at least 3 mm in diameter; Soluprick subcutaneous 10 HEP, ALK Laboratories, Hørsholm, Denmark), a history of at least 4 moderate-to-severe symptoms of SAR toward birch pollen (sneezing, itchy nose, runny nose, stuffy nose, watery eyes, red eyes, itchy eyes, or itchy throat) for a minimum of 2 years but none or only mild symptoms in the preceding month, and a baseline serum IgE level of 30 IU/mL or greater and less and/or equal to 700 IU/mL.

No subject was allowed the following: desensitization immunotherapy to birch pollen in the previous 2 years, a history of anaphylaxis, other types of rhinitis in the previous 3 months, infectious sinusitis in the previous month, or other relevant medical history in the previous 3 months.

Ethics Committee approval was obtained for each participating center. Each subject gave written informed consent before enrollment.

Study design

This randomized, double-blind, placebo-controlled, parallel-group trial was carried out at 14 centers (5 in Sweden, 5 in Finland, and 4 in Norway) between March and July 1998.

Subjects were screened 3 days to 4 weeks before randomization into the study. Eligible subjects were randomly allocated to receive rhumAb-E25 or placebo in a 2:1 ratio. They were assigned to one of two strata: those with a baseline serum IgE level of 150 IU/mL or less received 300 mg of rhumAb-E25 subcutaneously or placebo at baseline (week 0) and week 4, and those with a baseline serum IgE level of greater than 150 IU/mL received 300 mg of rhumAb-E25 subcutaneously or placebo at baseline and weeks 3 and 6. The injections were prepared by a person otherwise unconnected with the study and administered in the clinic.

Acrivastine, dexchlorpheniramine, or loratadine were provided for use as rescue medication; however, other antihistamines were permitted. No leukotriene receptor antagonist, 5-lipoxygenase inhibitor, or oral, nasal, or intramuscular corticosteroids within a specified washout period before screening or during the course of the trial. Inhaled low-dose corticosteroids for the treatment of asthma were allowed.

Daily pollen counts were measured locally. Start and end of the pollen season were defined as the first and last sequence of at least 2 consecutive days with a pollen count of greater than 10 grains/m³.

Efficacy outcome measures

Subjects completed a diary each evening during the 8-week double-blind treatment phase, recording the severity of each of 7 rhinoconjunctival symptoms (ie, sneezing, itchy nose, runny nose, stuffy nose, itchy eyes, watery eyes, and red eyes) by using a 4-point

scale (0, none; 1, mild; 2, moderate; and 3, severe) and documenting any use of rescue antihistamines or other SAR medication. The differences in duration of action of the antihistamines used in the study represented a hurdle for the quantitative assessment of rescue antihistamine intake. This was overcome by multiplying the daily intake of each antihistamine by a coefficient on the basis of the recommended dosing frequency. Chlorpheniramine was considered the standard and given a coefficient of 1; antihistamines with a longer duration of action were given coefficients of greater than 1. A coefficient of 1.3 was given to antihistamines with a recommended dosing frequency of 3 times daily (hydroxyzine hydrochloride 25 mg, acrivastine). A coefficient of 2 was given to antihistamines with a recommended dosing frequency of twice daily (dexchlorpheniramine maleate, pseudoephedrine sulphate, carbinoxamine maleate, and terfenadine 60 mg). A coefficient of 4 was given to antihistamines with a recommended dosing frequency of once daily (terfenadine 120 mg, loratadine, pseudoephedrine sulphate, cetirizine dihydrochloride, and ebastine). A coefficient of 0.57 was given to 10 mg of hydroxyzine hydrochloride (recommended up to 7 tablets daily). The adjusted values were referred to as *chlorpheniramine equivalents*. Subjects completed a rhinoconjunctivitis-specific quality of life questionnaire (RQLQ)²⁰ at baseline and at weeks 4 and 8 (for those dosed at 4-week intervals) or weeks 3, 6, and 8 (for those dosed at 3-week intervals). At the end of the double-blind treatment phase, subjects evaluated the overall efficacy of treatment using a 5-point scale (1, complete control of symptoms; 2, marked improvement; 3, discernible but limited improvement; 4, no appreciable change; and 5, worsening of symptoms).

Evaluation of IgE levels

Blood samples were collected for measurement of serum total and free IgE before dosing at baseline and at weeks 4, 8, and 20 or weeks 3, 6, 8, and 20 (for those dosed at 4-week and 3-week intervals, respectively).

Total IgE was measured by using a commercial kit (IMx Total IgE, Abbott Laboratories). The lower limit of quantitation was 2.4 ng/mL, and the coefficient of variation was 13.6% at 3.6 ng/mL. Free IgE was measured by using a solid-phase ELISA, as described by Casale et al,¹⁹ but with a fluorimetric technique with human serum as the standard. The coefficients of variation of the assay were from 5.4% to 11.2%. The lower limit of quantitation of this assay was 2 ng/mL, and the upper limit of quantitation was 150 ng/mL. The baseline value of total IgE was used as the free IgE level. Total IgE should be equivalent to free IgE before dosing other than differences in assay accuracy. The normal IgE level in an adult is approximately 90 IU/mL.²¹

Safety outcome measures

Adverse events were documented. Clinical laboratory tests (hematology, serum biochemistry, and urinalysis) were performed by a central laboratory at screening and weeks 0 (baseline) and 8. Subjects were closely monitored for signs or symptoms of anaphylactic reactions and indicators of immune complex disease. Subjects specifically recorded injection site reactions. Anti-rhumAb-E25 antibody levels (Fab) were measured by using solid-phase ELISA at baseline and week 20.¹⁹

Statistical analysis

The primary efficacy variable was the average daily nasal symptom severity score (average of the 4 individual nasal symptom scores: sneezing, itchy, runny, and stuffy nose) collected over the 8-week double-blind treatment phase. Secondary efficacy variables were the average daily ocular symptom severity score (average of the 3 individual ocular symptom scores: itchy, watery, and red

eyes), the average number of tablets of rescue antihistamines taken per day (chlorpheniramine equivalents), the proportion of days on which any SAR medication was taken, the QOL scores (7 domains and total), and the subjects' overall evaluation of treatment efficacy.

The data were analyzed with SAS software (version 6.09). The analyses of efficacy were performed according to the intent-to-treat method. Comparisons were based on the null hypothesis of no treatment difference and subjected to a two-sided test conducted at the .05 level of significance. Between-treatment analysis of the average symptom scores, average number of tablets of rescue antihistamine (chlorpheniramine equivalents), proportion of days with any SAR medication use, and QOL scores was performed by using analysis of covariance. Baseline value, treatment, center, and subgroup (based on baseline IgE) were included as factors in the model. QOL analysis was undertaken by using data from weeks 3 or 4 to correspond with the height of the pollen season; all other variables were averaged over the 8-week double-blind treatment period. Subjects' evaluation scores were analyzed by using the generalized Cochran-Mantel-Haenszel test, controlling for center.²²

To evaluate the relationship of free IgE levels at the end of the first dosing interval with measures of clinical effectiveness, subjects were classified into 4 groups on the basis of free IgE levels at weeks 3 or 4: 25 or less, >25-50, >50-150, and greater than 150 ng/mL. Separate analyses of covariance were performed for 3 clinical measures: average daily nasal symptom severity score, average number of rescue antihistamine tablets per day, and proportion of days with any SAR medication use. The free IgE group was the factor of interest, with a continuous covariant for predose total IgE and a categorical covariant for dosing regimen. The differences of the 3 lower groups relative to the highest group were estimated by using a *t* test without adjustment for multiplicity.

RESULTS

Baseline characteristics and accounting of patients

Two hundred fifty of the 251 randomized subjects received study treatment: 164 received rhumAb-E25 (165 randomized), and 86 received placebo. The baseline characteristics of the subjects were similar between treatment groups (Table I).

The start of the birch pollen season was at the end of April to the beginning of May, and the season continued into mid-June (Fig 1). Randomization was carried out over 4 weeks. Approximately 46% of the subjects were randomized more than 1 week before, 44% 1 week or less before, and 10% of the subjects after the start of the local pollen season.

Eleven subjects (3 receiving rhumAb-E25 and 8 receiving placebo) discontinued the study prematurely. Six subjects in the placebo group discontinued primarily because of unsatisfactory therapeutic effect compared with one subject in the rhumAb-E25 group. Three subjects discontinued because of protocol violations (two receiving rhumAb-E25 and one receiving placebo), and one placebo-treated subject was lost to follow-up. No subject discontinued as a result of adverse experiences.

Efficacy

The average daily nasal symptom severity score in the rhumAb-E25 group was similar at baseline and overall on treatment (ie, throughout the 8-week double-blind treat-

ment period), with mean values of 0.71 ± 0.05 ($\pm$ SE) and 0.70 ± 0.04 , respectively. In the placebo group it increased from 0.78 ± 0.07 at baseline to 0.98 ± 0.05 overall on treatment (difference in least-squares means [LSM], -0.23 ; $P < .001$; Fig 2). Average daily nasal symptom severity scores over time are illustrated in Fig 1.

The average daily ocular symptom severity score in the rhumAb-E25 group decreased from a mean of 0.47 ± 0.05 at baseline to 0.43 ± 0.03 overall on treatment compared with a mean increase in the placebo group from 0.43 ± 0.06 at baseline to 0.54 ± 0.04 overall on treatment (difference in LSM, -0.09 ; $P = .031$).

The average number of tablets of rescue antihistamines (chlorpheniramine equivalents) taken per day was lower in the rhumAb-E25 group (0.59 tablets per day) than in the placebo group (1.37 tablets per day; difference in LSM, -0.78 tablets per day; $P < .001$). The proportion of days on which any SAR medication was taken was almost twice as high in the placebo group as in the rhumAb-E25 group: 49% versus 28%, respectively (difference in LSM, -0.21 ; $P < .001$).

Statistically significant differences in favor of rhumAb-E25 were observed in each of the 7 domains of the RQLQ and in the total RQLQ score (Table II). Clinically meaningful differences over placebo ($>.05$ units)²³ were reached in total score and in the domains of activities, nasal symptoms, non nose-eye symptoms and practical problems and were approached in the domain of sleep. Subjects' overall evaluation of treatment effectiveness similarly favored rhumAb-E25 over placebo ($P = .001$). Twenty-one percent of subjects treated with rhumAb-E25 considered that their treatment gave complete control of symptoms compared with 2% of placebo-treated subjects, whereas a further 59% receiving rhumAb-E25 reported improvement compared with 35% receiving placebo. Only 3 (2%) subjects who received rhumAb-E25 considered their symptoms worsened compared with 11 (13%) who received placebo.

IgE levels and clinical outcomes

In subjects treated with rhumAb-E25, free IgE levels in serum at weeks 3 or 4 were below 25 ng/mL in 113 (69%) subjects and only exceeded 50 ng/mL in 3 (1.8%) subjects. Free IgE levels in serum at weeks 3 or 4 exceeded 50 ng/mL in all but one placebo-treated subject. Significant differences in favor of a better clinical outcome were observed in subjects with free IgE below 25 ng/mL compared with higher free IgE groups (Table III).

Birch pollen-specific IgE levels were measured only at baseline and were similar for the two treatment groups (mean of 20.05 IU/mL and 19.82 IU/mL for rhumAb-E25 and placebo, respectively).

Safety

Recombinant humanized mAb-E25 was well tolerated. There were no clinically important laboratory findings. Adverse events were reported during treatment in 36% of rhumAb-E25-treated subjects compared with 37% of placebo-treated subjects. The adverse event pro-

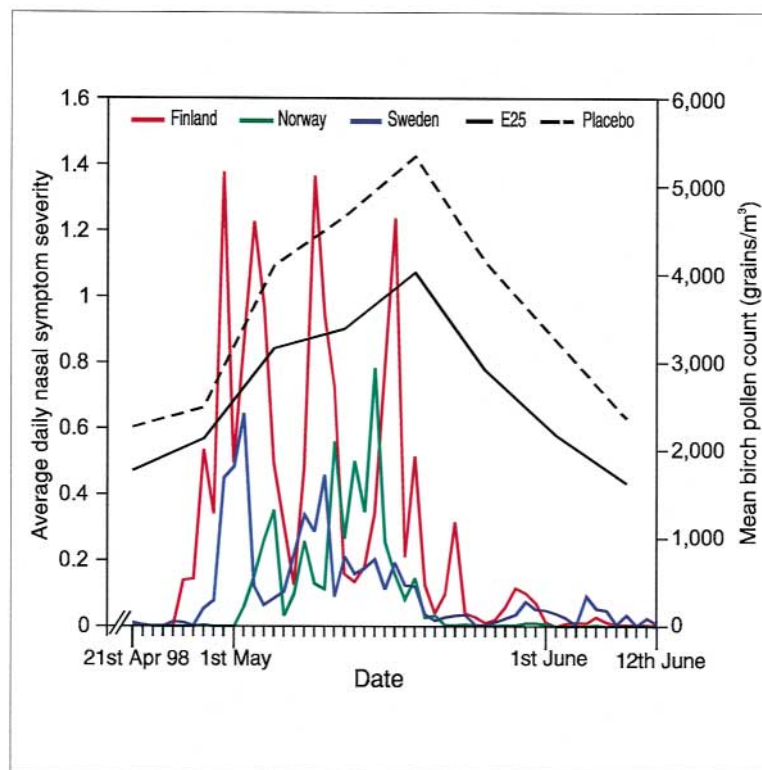


FIG 1. Average daily birch pollen counts and nasal symptom severity scores throughout the birch pollen season in Finland, Norway, and Sweden.

TABLE I. Baseline characteristics for all randomized subjects

Characteristic	rhumAb-E25 (n = 165)	Placebo (n = 86)
Age (y)		
Mean $\pm$ SD	33 $\pm$ 10.4	34 $\pm$ 10.1
Range	17-66	19-64
Female sex (%)	52	56
Caucasians (%)	99	97
Height (cm)		
Mean $\pm$ SD	173 $\pm$ 9.8	173 $\pm$ 8.6
Range	150-200	156-191
Weight (kg)		
Mean $\pm$ SD	73 $\pm$ 13.7	74 $\pm$ 13.1
Range	48-110	50-99
Baseline IgE (IU/mL)		
Mean $\pm$ SD	144 $\pm$ 124.3	143 $\pm$ 124.5
Range	31-681	30-714
>150 IU/mL (%)	35	34
History of asthma (%)	35	31
Inhaled corticosteroids to treat asthma (%)	7	7
History of atopic dermatitis (%)	28	21

file of rhumAb-E25 was similar to that of placebo. There were no anaphylactic-anaphylactoid reactions or other serious drug-related adverse events and no evidence of immune complex disease. Injection site reactions occurred with a similar frequency after rhumAb-E25 and placebo (12.2% vs 10.3%, respectively). Three subjects reported a total of 4 episodes of a localized urticaria after rhumAb-E25 administration (0.52% of rhumAb-E25

injections); all were mild and resolved without treatment. No anti-rhumAb-E25 antibodies were detected.

DISCUSSION

This randomized, double-blind, placebo-controlled trial showed that rhumAb-E25, a humanized anti-IgE mAb, was well tolerated and effective in preventing and

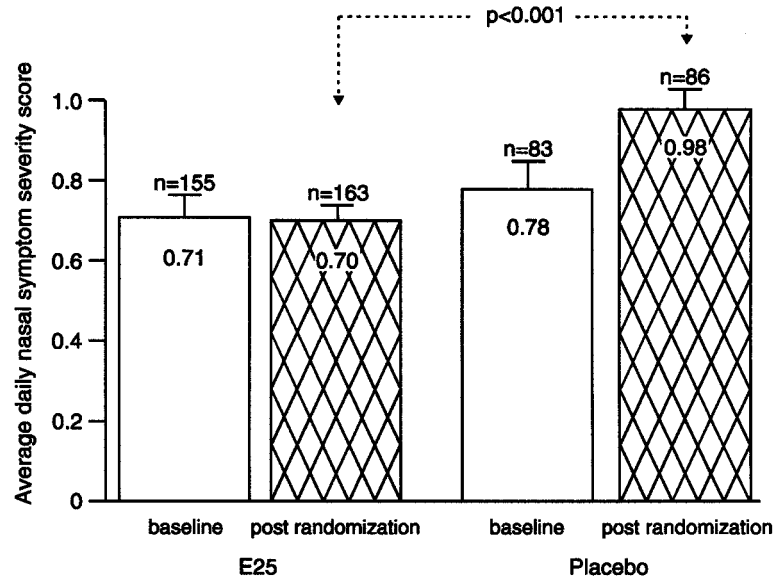


FIG 2. Average daily nasal symptom severity scores (with SEs) over the entire postrandomization period (all randomized subjects in an intent-to-treat analysis). The baseline levels are not equal to the first point indicated in Fig 1 because baseline values were spread over a number of different dates.

TABLE II. RQLQ score at week 3 or 4

Domains	rhumAb-E25 (n = 153)	Placebo (n = 78)	Difference ($\pm$ SE)	P value
RQLQ total	1.75	2.30	-0.55 (0.15)	<.001
Activities	2.46	3.39	-0.93 (0.22)	<.001
Sleep	1.17	1.64	-0.48 (0.17)	.006
Non-nose/eye symptoms	1.44	2.07	-0.63 (0.17)	<.001
Practical problems	2.30	2.86	-0.56 (0.20)	.006
Nasal symptoms	2.10	2.81	-0.70 (0.17)	<.001
Eye symptoms	1.68	2.04	-0.36 (0.17)	.036
Emotional	1.06	1.46	-0.40 (0.15)	.007

Data displayed are LSMs. Clinically meaningful differences (>0.5 units) are given in bold. Details are given elsewhere.^{20,23}

TABLE III. Relationship between clinical efficacy variables and free IgE concentration groups (all treated subjects)

Efficacy variable (entire post- randomization period)	Free IgE concentration group	Total No. of patients	Mean	LSM difference (SE) relative to group 4	P value relative to group 4
Average daily nasal symptom severity score	1: ≤ 25 ng/mL	113	0.68	-0.37 (0.08)	<.001
	2: >25 -50 ng/mL	48	0.77	-0.25 (0.10)	.010
	3: >50 -150 ng/mL	33	0.86	-0.20 (0.11)	.056
	4: >150 ng/mL	54	1.03		
Average daily number of tablets of rescue antihistamine	1: ≤ 25 ng/mL	113	0.46	-1.07 (0.18)	<.001
	2: >25 -50 ng/mL	49	0.58	-0.84 (0.21)	<.001
	3: >50 -150 ng/mL	33	0.87	-0.64 (0.24)	.008
	4: >150 ng/mL	54	1.49		
Proportion of days with SAR medication use	1: ≤ 25 ng/mL	113	0.22	-0.27 (0.05)	<.001
	2: >25 -50 ng/mL	49	0.27	-0.22 (0.06)	<.001
	3: >50 -150 ng/mL	33	0.37	-0.13 (0.06)	.041
	4: >150 ng/mL	54	0.49		

controlling symptoms of pollen-induced SAR, while reducing the use of rescue and concomitant SAR medication, and had a positive effect on QOL.

Our study covered an 8-week observation period, with all study days included in the analysis, independent of the pollen counts. This time period was considered nec-

essary to maximize the likelihood of dosing subjects before the start of the birch pollen season and encompass the whole season in all centers. As it turned out, the 1998 birch pollen season in the participating Nordic European countries (Finland, Norway, and Sweden) started early, with imported birch pollen carried over by winds from

central Europe; that is, pollen exposure frequently coincided with or, in some cases, preceded the first dose of trial medication. With high pollen counts and this early onset of exposure, the 1998 birch pollen season had a long duration. The inclusion in the analysis of all days falling in the 8-week observation period, including those with low pollen counts, together with the relatively late start of the experimental treatment relative to the start of the season in some subjects, may have masked some of the beneficial effect of rhumAb-E25.

A significant between-treatment difference in favor of rhumAb-E25 was documented for the average daily nasal symptom severity score, the primary efficacy outcome variable of our study, which combined severity scores of the 4 main nasal symptoms (sneezing, itchy, runny, and stuffy nose). In subjects who received rhumAb-E25, there was almost no change from baseline in average daily nasal symptom severity score, whereas the group who received placebo showed an increase (ie, worsening) from baseline. The difference between groups in average daily ocular severity score was smaller compared with the nasal scores but also achieved statistical significance in favor of rhumAb-E25.

The positive effect of rhumAb-E25 on symptoms must be interpreted in relation to the intake of SAR medication. We found that the group receiving rhumAb-E25 took on average less than half the number of rescue antihistamine tablets (chlorpheniramine equivalents) per day than the group receiving placebo. During the trial, the subjects also took a variety of SAR medications other than rescue antihistamines. This was accounted for by evaluating the proportion of days in which any SAR medication was used. As with the use of rescue antihistamines, the days on which any SAR medication was taken were almost half as frequent in the rhumAb-E25 group than in the placebo group.

Subjects treated with rhumAb-E25 not only had significantly less severe symptoms but also took significantly less SAR medication compared with placebo-treated subjects. This combined effect strengthens the efficacy results of our trial. The greater intake of antihistamines and other SAR medication by placebo-treated subjects probably reduced symptom severity of the placebo group during the pollen season, as well as the magnitude of the differences between placebo and rhumAb-E25. Eventually, studies need to be conducted in which rhumAb-E25 is compared with intranasal corticosteroids, which have documented positive effects on prevention and control of allergic rhinitis.²⁴ The combined effect of the two therapeutic approaches, which have different and possibly complementary mechanisms of action, should also be investigated.

Casale et al¹⁹ postulated that if sufficient quantities of rhumAb-E25 were given to fully suppress free IgE in serum, then SAR symptoms would likely decrease. Using 300 mg of rhumAb-E25 given subcutaneously twice at monthly intervals or 3 times at 3-week intervals depending on baseline IgE levels, we achieved a reduction in free IgE levels to below or near the crucial level suggested by Casale

et al (<25 ng/mL). We also found an association between free IgE levels and measures of clinical effectiveness.

The short-term safety profile of rhumAb-E25 was very good. There was no evidence of immune complex disease during the study and no clinical or laboratory indication of hemolysis. The other main safety concerns after antibody administration are those of anaphylactic reactions and skin hypersensitivity. No anaphylactic or anaphylactoid reactions were observed, and the only reports consistent with skin hypersensitivity reactions were from 3 subjects who had mild local urticaria. The adverse event profile of rhumAb-E25 was otherwise similar to that of placebo. These data support the findings from previous clinical studies that rhumAb-E25 is well tolerated.^{19,25-27}

Three sets of measurements collected in our trial strongly suggest that the efficacy and tolerability of rhumAb-E25 translated into a meaningful advantage for the subjects during this severe and long pollen season. The first was the RQLQ, a disease-specific QOL questionnaire developed and validated by Juniper et al.^{20,23} Results showed statistically significant differences in favor of rhumAb-E25 for the total score and all 7 domains of the RQLQ. These differences also reached or surpassed the proposed threshold of clinical relevance (≥ 0.5 units)²³ for total score and most domains, including those related to activities and practical problems. The second comprehensive indicator of clinical benefit was the subjects' overall opinion of the effectiveness of the treatment. Marked superiority of rhumAb-E25 over placebo was documented, with 21% of subjects receiving rhumAb-E25 versus 2% receiving placebo reporting that their treatment gave complete control of their symptoms. Finally, 6 of 7 discontinuations because of unsatisfactory therapeutic effect, a clear expression of dissatisfaction with treatment, occurred in the placebo group.

An investigation into the effect of aerosolized rhumAb-E25 antibody administered to subjects with mild allergic asthma has recently been published. Fahy et al²⁸ found that administration by this route did not result in a significant change in serum IgE levels despite detectable levels of rhumAb-E25 and did not affect the early phase response to allergen. Thus the route of administration of rhumAb-E25 may be important in the efficacy profile of rhumAb-E25.

In conclusion, the use of the humanized monoclonal anti-IgE antibody rhumAb-E25 administered subcutaneously appears to represent a safe and effective therapeutic option in the treatment of SAR. Because there is no allergen specificity, anti-IgE treatment could be used to treat multiple allergic conditions simultaneously. Recent data suggest that rhumAb-E25 could also be a useful treatment in allergic asthma.²⁵⁻²⁷ The infrequent administration of rhumAb-E25 may add to the benefit of this therapeutic approach.

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