

## **Epidemiological characteristics and allergen sensitization patterns in subjects with intermittent allergic rhinitis in the international ACCEPT1 study in association with GA<sup>2</sup>LEN**

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**Background:** Under the ARIA guidelines, allergic rhinitis (AR) is classified as intermittent (IAR) or persistent (PER) disease depending on the duration of symptoms. In addition, AR may co-exist with or exacerbate allergic co-morbidities. As part of a prospective study of desloratadine (DL) in the treatment of IAR, we studied the epidemiology of concomitant allergic diseases and allergen sensitization patterns internationally.

**Methods:** This was a multi-national, randomized, placebo-controlled, parallel-group study of DL 5mg and Placebo QD administered for 15 days in subjects with ARIA-defined IAR. At screening, subjects underwent skin testing for sensitization to prevalent allergens; where possible the GA<sup>2</sup>LEN allergen panel was employed. Eligible subjects were aged  $\geq 12$  yrs, had a diagnosis in keeping with IAR for  $\geq 2$  yrs and were skin-test positive (wheal  $> 3$ mm more than diluent control) to  $\geq 1$  relevant allergen. Subjects had to have symptomatic IAR at screening. Demographic and concomitant allergic disease characteristics were recorded at screening; these data and allergen skin-test responses were pooled for the entire population and were reported descriptively.

**Results:** The study enrolled 547 subjects in 14 countries in Europe (incl. Russia and Turkey) and Canada. Overall 58% of the population was female and 91% was Caucasian. The mean ( $\pm$ SD) age was  $34.2 \pm 12.4$  yrs (range: 13-72 yrs), while the mean height and weight were  $169.5 \pm 9.3$  cm and  $71.2 \pm 15.5$  kg, respectively. Overall, 16.8% reported having allergic asthma, 15.2% reported concomitant food allergy and 10.6% had atopic dermatitis. Among the entire study population the most frequent relevant positive skin-prick tests were as follows: grass mix (40.1%), *D. pteronyssinus* (37.9%), *D. farinae* (31.7%), cat (22.5%), birch (22.3%), hazel (17.6%), alder (16.3%), ragweed/ambrosia (15.8%), dog (12.6%), parietaria (9.5%) and alternaria (8.61%). Among European countries, allergen sensitization frequencies were as follows: grass mix (57.1%), *D. pteronyssinus* (36.3%), *D. farinae* (29.4%), birch (28.3%), cat (23.6%), hazel (20.1%), alder (15.9%), dog (15.1%), parietaria (14.3%) and artemisia (11.5%).

**Conclusion:** In subjects with ARIA-defined IAR, allergic co-morbidities of the lower airway, gut and skin were also prevalent. Subjects with IAR demonstrate sensitization to a variety of seasonal and year-round allergens; geographical differences in allergen sensitization patterns were seen.

## **Updosing of desloratadine results in better improvement of temperature and exposure time thresholds in patients with cold urticaria**

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**Background:** Currently, patients with acquired cold urticaria (ACU) are ideally treated with non-sedating antihistamines (nsAHs), e.g. desloratadine, as recommended by the EAACI/GA<sup>2</sup>LEN/EDF guidelines. These guidelines also recommend increasing the dosages of nsAHs in patients that do not respond satisfactorily to standard doses. This recommendation is, however, not evidence based as, to date, there are no controlled studies to support the efficacy of up-dosing nsAH in ACU.

**Methods:** In this study, thirty ACU patients were treated with desloratadine 5mg/day, 20mg/day, and placebo for seven days in a double-blind crossover trial. At screening, and after every treatment phase, the critical temperature thresholds (CTTs) and the critical stimulation time thresholds (CSTTs) were measured by cold provocation testing with TempTest 2.0. To determine the CTTs, patients were exposed to different temperatures (range 4°C to 30°C) for 5 min. To assess the CSTTs, TempTest 2.0 was applied to the skin at 4°C for different lengths of time ranging from 0.5 min to up to 5 min. Confluent whealing at the test site 10 min after cold provocation was considered a positive test reaction and results were calculated as means  $\pm$  standard errors.

**Results:** Treatment with both desloratadine 5mg/day and desloratadine 20mg/day resulted in significant reductions in CTTs and increases in CSTTs as compared to placebo (both doses:  $p < 0.001$ ). Notably, desloratadine 20mg/day showed a significant improvement in these parameters as compared to desloratadine 5mg/day (CTT:  $p = 0.001$ , CSTT:  $p < 0.001$ ). Desloratadine 5mg/day reduced CTTs by  $6.0 \pm 1.2^\circ\text{C}$  and increased CSTTs by  $1.4 \pm 0.4$  min, whereas desloratadine 20mg/day reduced CTTs by  $10.3 \pm 1.6^\circ\text{C}$  and increased CSTT by  $2.9 \pm 0.4$  min. Corresponding values for placebo were a reduction in CTTs of  $0.7 \pm 0.4^\circ\text{C}$  and an increase in CSTTs of  $0.2 \pm 0.2$  mins.

**Conclusions:** Desloratadine at its standard dose (5mg/day) effectively improved the time and temperature thresholds versus placebo in ACU patients. Up-dosing desloratadine to 20mg/day significantly improved this benefit, indicating that higher doses may be clinically useful in ACU patients that do not respond satisfactorily to standard doses.

## Use of and satisfaction with prescription medications for treatment of chronic urticaria

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**Background:** Patients with chronic urticaria (CU) often experience multiple negative effects, including fatigue due to lack of quality sleep, recurrent pain syndromes, and insomnia. Since there are numerous prescription and non-prescription treatments available for CU, this study was undertaken to determine which treatments patients prefer, their willingness to switch to another treatment, and preference for prescription versus over-the-counter (OTC) treatments for CU, and to understand whether patients who perceive relief are more likely to prefer and use certain types of treatments.

**Method:** Data were collected online from patient panels in France and Germany from Oct. 16 - Nov. 13, 2006. Both panels are representative of the general population for their respective country. Respondents had suffered an outbreak of chronic urticaria (defined as an outbreak lasting 6 weeks or more) at least once in the past 12 months.

**Results:** The final sample consisted of 405 respondents: 197 interviews completed in France; 208 in Germany. Patients who are more satisfied with their treatment are less likely to want to try a new treatment. Patients who use prescription treatment are more satisfied with their treatment than are those who use OTC medicines. Patients in Germany, where it is more common than in France to encourage generic substitution for treatment, are more likely to be satisfied with their brand name treatment than OTC or other treatments.

**Conclusions:** Patients prefer prescription medications for their CU over OTC or other treatments such as lotions, baths, ice, or home remedies. Patients are generally less likely to want to try new treatments if their current regimen works, and those who use prescription medications are more satisfied with their treatment than those who use OTC treatments or home remedies. These results suggest that brand name prescription medications are preferred by patients with CU.

## Desloratadine significantly reduces nasal congestion and other individual symptoms scores in subjects with intermittent allergic rhinitis: The ACCEPT1 Study in collaboration with GA<sup>2</sup>LEN

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**Background:** The ARIA guidelines define intermittent allergic rhinitis (IAR) in patients with symptoms for <4 days/week or for <4 consecutive weeks. Nasal congestion is a prominent and troublesome symptom of AR. The efficacy of desloratadine (DL) in the treatment of AR (including nasal congestion) has been demonstrated in multiple clinical studies but has not, to date, been studied in subjects with IAR.

**Methods:** This was a prospective, randomized, multi-national, placebo-controlled, parallel-group study of the safety and efficacy of DL 5mg or Placebo QD for 15 days in subjects with IAR. Eligible subjects were aged ≥12 yrs, had a diagnosis consistent with IAR for ≥2 yrs and had a positive allergen skin-prick test. Nasal congestion, sneezing, rhinorrhea, nasal pruritus and ocular pruritus were rated on 4-point scales (0=none; 3=severe). Symptoms severities were rated AM and PM as current (NOW) and over the past 12 hours (PRIOR). Endpoints included changes from baseline in mean AM/PM PRIOR and AM NOW (end of 24-hr dosing period) symptoms scores over the 2-week study period. Adverse events (AE) were classified by severity and potential relation to treatment.

**Results:** The DL (n=276) and Placebo (n=271) groups were matched at baseline. A significantly greater improvement from baseline in average AM/PM PRIOR nasal congestion scores over days 1-15 was seen with DL vs. Placebo (-0.56 vs. -0.43, respectively; P=0.013). This benefit favoring DL was seen as early as Day 1 of treatment (P=0.004). Nasal congestion was significantly lower with DL vs Placebo at the end of the first 24-hr dosing interval (AM NOW Day 2; P≤0.001). Mean AM/PM PRIOR scores for rhinorrhea, sneezing and nasal itching were also significantly lower with DL vs. Placebo on Day 1, over week 1, week 2 and over days 1-15 (P≤0.033). Eye itching was significantly lower in the DL group over week 1 (P=0.021) and was numerically lower over Days 1-15 (P=0.051). Rhinorrhea, sneezing, eye itching and nasal itching scores at the end of the 24-hr dosing period (AM NOW) were significantly lower with DL at Day 2 (end of the 1st 24 hr interval; P≤0.035) and over Days 2-15 (P≤0.036). AE rates were similar in the DL and Placebo groups.

**Conclusions:** This is the first prospective study demonstrating that DL significantly reduces nasal congestion and other symptoms scores in subjects with ARIA-defined IAR. Effects on nasal congestion and other IAR symptoms were seen during the 1st full day of treatment.

**A combination of desloratadine 2.5 mg and pseudoephedrine 120 mg BD is more effective than the individual components for the treatment of allergic rhinitis: evidence from randomized, double-blind clinical trials**

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**Background:** Nasal congestion is rated by patients as the most troublesome symptom of allergic rhinitis (AR). Desloratadine (DL), a potent, non-sedating, selective H1-receptor antagonist reduced nasal congestion in clinical trials; but in patients with nasal congestion that is not adequately controlled by DL therapy alone, the combination with pseudoephedrine (PSE) can improve symptomatic control. Such combination can provide an additive, greater therapeutic response than either component alone.

**Methods:** Two multicenter, double-blind, randomized, parallel-group studies compared the efficacy and safety of a combined DL 2.5mg/PSE 120mg tablet (DL-D12) BID for 15 days vs. the individual components alone in the treatment of subjects with symptomatic seasonal AR. Subjects aged ≥12 years of either sex or any race, with a history of seasonal AR for ~2 yr confirmed by a positive skin-prick test. Symptom scores were recorded each AM and PM in patient diaries. The primary endpoint for the antihistamine component (DL-D12 vs PSE) was the mean change from baseline in the average AM/PM total symptom score (TSS), excluding nasal congestion, over the 2 weeks of the study. The primary endpoint for the decongestant component (DL-D12 vs DL) was the mean change from baseline in the average nasal congestion score over the 2 weeks of the study. Adverse event (AE) reports and changes in vital signs and ECGs were noted..

**Results:** The studies included 1248 subjects (64.3% female); the treatment groups were similar at baseline. In both studies, the antihistaminic effect (TSS excluding nasal congestion) of DL-D12 was significantly greater than that of PSE alone (P<0.001), and the decongestant effect of DL-D12 was significantly greater than that of DL alone (P<0.005). From Day 1 onwards the antihistaminic and the decongestant effects of DL-D12 at the end of the 24-hour dosing interval were significantly greater than those for PSE and DL, respectively (P≤0.019). DL-D12 was well tolerated. Overall AEs rates were similar in the three study groups in both studies; AEs with DL-D12 were similar to those with PSE (headache, insomnia). Minor increases in mean heart rate occurred in the DL-D12 and PSE groups. No clinically relevant changes in any ECG parameters were noted.

**Conclusion:** DL-D12 was well tolerated and was significantly more effective than either component alone in the treatment of all AR symptoms. For patients with nasal congestion, DL-D12 represents a useful therapeutic option.

**Treatment of allergic rhinitis with desloratadine: results of observational study in the gulf region using symptom score and peak nasal inspiratory flow**

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**Background:** Allergic Rhinitis is highly prevalent in Gulf States; this study evaluates the effectiveness and safety of Desloratadine (DL), an H1-blocking antihistamine, in improving the manifestations of Allergic Rhinitis (AR) in Arab and Asian populations.

**Methods:** A Two-week, multicenter, study conducted in UAE, Kuwait, Qatar, Oman and Bahrain using oral DL 5 mg once daily in the morning. Patients at baseline visit aged ≥ 12 years and presented by clinically symptomatic moderate to severe Seasonal or Perennial AR with total symptom score (TSS) ≥ 8 including a nasal stuffiness score of ≥ 2 (i.e. moderate to severe) and the non-nasal symptom score ≥ 2. Nasal stuffiness was assessed objectively by measuring Peak Nasal Inspiratory Flow (PNIF) using Portable Nasal Inspiratory Flow Meter. Symptoms of AR were again assessed in the second visit conducted after 2 weeks of treatment (final visit) together with PNIF measurement. Data analysis done on Intent to treat base using Wilcoxon matched-pairs signed-rank test.

**Results:** 602 patients recruited (60% males), 50 % Arab and 37 % Asian, with a mean age 33.7 ± 12.09 years. 67.5% of patients diagnosed Seasonal AR and 32.5% diagnosed Perennial AR. DL significantly reduced all mean individual symptom scores and TSS (see Table 1). Investigator and patient Global Therapeutic assessment: 85.2% of patients had complete or marked relief, 12.6% moderate relief and no relief in 2.2 %. There was no treatment discontinuation or serious adverse effects related to DL. Table 1 Decrease in AR Symptoms scores with DL therapy

Symptoms	Symptom score Pretreatment (mean)	Symptom score Post-treatment (mean)	Decrease (%)
Nasal discharge	2.01	0.44	78.1*
Nasal stuffiness	2.16	0.62	71.3*
Sneezing	1.93	0.35	81.9*
Nasal itching	1.74	0.30	82.7*
Ocular symptoms	1.23	0.17	86.2*
TSS	8.91	1.86	79.1 *
PNIF score	88.1	151.4	41.8* †

\* P<0.0001 † increase (%).

**Conclusion:** This study supports the evidence from controlled clinical trials that DL is effective and well tolerated in controlling the manifestations of AR, including nasal stuffiness.

## **Aerius control: Clinical and evaluative profile of treatment (ACCEPT): A comprehensive GA<sup>2</sup>LEN-collaborative study program of desloratadine therapy in the management of intermittent and persistent allergic rhinitis**

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**Background:** The ARIA guidelines classify allergic rhinitis (AR) based on the duration of symptoms and their impact on the patient's life. Intermittent and persistent AR (IAR and PER, respectively) are treated in a stepwise fashion according to the ARIA guidelines, with non-sedating antihistamines being a first-line therapy. Desloratadine (DL) has previously been shown to be effective in the treatment of seasonal and perennial AR. However, prospective data on DL in the setting of ARIA-defined IAR and PER have not, to date, been available.

**Methods:** The ACCEPT program consists of two multi-national, prospective, randomized, placebo-controlled studies of DL 5 mg in subjects aged  $\geq 12$  yrs with ARIA-defined AR. One study assessed the effect of DL 5mg QD vs. Placebo administered for 15 days in subjects with IAR. The other study assessed DL 5 mg or Placebo QD administered for 12 weeks in subjects with PER. All subjects had to have ARIA-defined IAR or PER for  $\geq 2$  yrs that was active at Baseline and also had to demonstrate a positive skin-prick test to  $\geq 1$  relevant allergen, preferably using the GA<sup>2</sup>LEN allergen panel. In both ACCEPT studies the primary endpoint was the mean change from baseline in the daily average of morning (AM) and evening (PM) (prior 12-hours) 5 symptom scores (T5SS). In the IAR study this was averaged over Days 1-15 and in the PER study it was averaged over Days 1 to 29. Secondary criteria included safety, the impact of DL treatment on important disease measures such as the Rhinoconjunctivitis Quality of Life Questionnaire, individual symptom scores, a symptoms severity visual analog scale (VAS) and effects on rhinitis-impaired sleep, daily activities, and productivity.

**Results:** Participating countries in the ACCEPT studies included Canada, France, Germany, Italy, Spain, Italy, Denmark, Belgium, the Netherlands, Hungary, Greece, Finland, Portugal, Turkey and Russia. The IAR study has been completed and demonstrated that DL was well tolerated and was associated with significant improvements from baseline vs. Placebo in mean AM/PM T5SS over Days 1-15 (primary endpoint), individual symptoms including nasal congestion, RQLQ; a beneficial effect was also seen in terms of the work productivity and activity index.

**Conclusion:** ACCEPT is the first prospective study program performed in collaboration with GA<sup>2</sup>LEN to determine the safety and efficacy of the first-line therapy, desloratadine, in the management of ARIA-defined IAR and PER.

### **Desloratadine therapy in atopic diseases**

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**Background:** Incidence of allergic and respiratory disease is increasing all over the world. Prevalence of bronchial asthma and allergic rhinitis increased markedly in Hungary, similar to increases reported in European and other industrial nations, as well as in developing countries. This study was undertaken between February 2005–2006 to investigate the effect of desloratadine (DL) on these different atopic diseases.

**Method:** A total of 196 children aged 2-18 years participated in the study. Subjects were randomised to receive either DL or placebo. Allergen sensitivity was investigated using skin-prick test, and total serum levels of IgE, GM-CSF, TNF-alpha, IL-6, and ICAM-1 were determined. Symptom scoring was created and each patient kept a diary to evaluate symptoms. Symptoms in both the DL and placebo groups were assessed at baseline, and again at one and three months into treatment. Liver enzyme function values were assessed after three months.

**Results:** A decrease in symptoms in subjects receiving DL could be detected after Week 1. Significant amelioration of allergic rhinitis, atopic dermatitis, and bronchial asthma was observed after one month. Liver enzyme function values did not increase, even after long-term administration of DL; liver enzyme values remained within the normal range. Serum markers of atopic inflammation showed a rather good correlation with the severity of the disease. ICAM-1 values were highest in cases of viral infection (rhinosinusitis). Side-effects were recorded in two subjects. One subject experienced a slight headache; another subject complained of abdominal pain during administration of DL syrup.

**Conclusion:** Desloratadine is an effective treatment that significantly decreases symptoms of allergic disease.

## **A multinational European survey of parents' attitudes to the severity and management of pediatric allergies and new therapeutic options**

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**Background:** Allergies are one of the most frequent chronic conditions affecting the juvenile population but little is known about parents' medication choices for treatment of their children's allergies. A multinational European survey was undertaken to address this issue and to assess attitudes to novel pediatric formulations of the antihistamine, desloratadine (DL).

**Methods:** This online survey was conducted in July 2007 in parents in France (n=150), Italy (n=160), the Netherlands (n=157) and Spain (n=160). Subjects had to have a child <12 yr with an allergy or hives  $\geq$ 1 week/yr. Subjects were identified following screening by the Forbes Consulting Group. Data related to the child's allergy symptom severities and preferences regarding types of allergy therapies were collected.

**Results:** Overall, 20-24% of households had children aged <12 with allergies. Allergy severity was rated differently by country, with more Dutch respondents reporting severe symptoms (22%) versus parents in Spain (11%), Italy (9%) and France (5%). Most parents reported their child's allergies as being of moderate severity (50-69%). Prescription medications were used most/all of the time by 68-96% of parents, although in some countries sedating antihistamines were still used frequently. Good efficacy (57-82%), ease of administration (14-27%) and ingredients/side effects (12-28%) were rated as important attributes of current therapy. Syrups/liquids were commonly used in Spain (74%) and France (71%), while oral drops (42%) and syrups/liquids (44%) were favored in Italy, and tablets/capsules were most frequently used by parents in the Netherlands (50%). Regarding DL, parents reported a high likelihood of trying new formulations for their children's allergies (Spain: 74-84%; France: 71%; Italy: 68-70% and the Netherlands: 51-54%). For oral dispersible DL tablets, convenience was an important consideration for use in 80% of respondents. For DL syrup, the lack of sugar and artificial dyes/colors were rated as important by 73.7% and 73% of respondents, respectively. Most parents (60-88%) rated it important that new formulations be healthier choices than current medications.

**Conclusions:** In this survey, 20-24% of households had a child <12 years with an allergy, for which parents frequently used prescription medications. Healthiness and convenience as being important reasons for using new formulations of DL to treat their children's allergies.

## **Desloratadine Improves disease-specific quality of life and reduced symptom burden measured with a novel visual analog scale in patients with intermittent allergic rhinitis; Results of the ACCEPT1 study in collaboration with GA<sup>2</sup> LEN**

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**Background:** Allergic rhinitis (AR) is associated with recurrent symptoms that impair quality of life (QOL). AR is classified under ARIA as intermittent (IAR) or persistent disease. Desloratadine (DL) is a first-line therapy in AR, but its effects in QOL in IAR have not been studied previously.

**Methods:** This was a prospective, randomized, multi-center, multi-national, parallel-group, placebo-controlled study of the safety and efficacy of desloratadine 5mg or Placebo QD for 15 days in patients with IAR. Subjects had to be aged  $\geq$ 12 yr, have a confirmed AR diagnosis for  $\geq$ 2yrs consistent with IAR and have a positive skin test to  $\geq$ 1 prevalent or GA<sup>2</sup>LEN panel allergens. In subjects  $\geq$ 18 yrs, QOL was measured at baseline and at the study endpoint using the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), which has a minimal important difference (MID) of 0.5 points. Effects of IAR on sleep and daily activities were scored on 4-point scales once daily AM and PM, respectively. A visual analog scale (VAS) was used to assess IAR severity once daily (AM) based on the prior 24 hrs (0mm=not bothersome; 100mm=very bothersome). Adverse events (AE) were rated by severity and relation to study drug.

**Results:** The DL and Placebo groups were balanced at baseline. A significantly greater improvement (decrease) from baseline in total RQLQ score was seen in the DL group versus Placebo at the study endpoint (-1.10 (-38.2%) vs. -0.73 (-24.9%);  $P < 0.001$ ). The RQLQ domains of activity, non-nose/eye symptoms, practical problems, nasal symptoms, eye symptoms and emotion scores were also significantly improved with DL versus Placebo ( $P \leq 0.007$ ). Subjects with higher baseline diary total 5-symptoms scores ( $\geq 8.5/15$ ) had larger improvements from baseline in total RQLQ with DL versus Placebo, with an effect size (0.55) greater than the MID. There was a significantly greater decrease from baseline in the VAS score with DL versus Placebo (-17.2 (-30.6%) vs. -10.9 (-17.0%);  $P < 0.001$ ); the VAS score was significantly improved with DL on all treatment days. The DL group also had greater improvements from baseline in scores for sleep and daily activity disruption over the duration of the study ( $P \leq 0.039$ ). DL was well tolerated and had a similar AE profile to Placebo.

**Conclusions:** DL significantly improved QOL and decreased sleep and daily activity impairment in subjects with IAR. A new VAS of symptom burden showed significant improvements with DL on every study day.

### **Observational study evaluating nighttime and early morning treatment satisfaction in patients receiving once daily desloratadine for seasonal allergic rhinitis in routine daily practice in Saudi Arabia**

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**Background:** In some studies, Allergic Rhinitis (AR) symptoms have shown a circadian rhythm with morning symptoms being most prominent in the majority of patients. At nighttime, both the symptoms and the underlying pathology of AR might contribute to sleep disturbance.

**Objective:** To assess the nighttime and early morning treatment satisfaction of SAR patients treated with desloratadine (DL) 5 mg QD when prescribed in routine daily practice irrespective of the dosing time (AM or PM).

**Methods:** This was a multicenter observational study. Patients with clinically symptomatic SAR received DL 5 mg once daily. Demographics, baseline and post-treatment SAR symptom scores; post-treatment nighttime and early morning patient's satisfaction; global therapeutic response and adverse events were recorded for each patient. Patient's satisfaction was assessed using VAS score from 0 to 100 (0-50=unsatisfied, 51-75=fairly satisfied, 76-85=very satisfied and 86-100=extremely satisfied). SAR symptoms (i.e. rhinorrhea, nasal congestion, sneezing, itching nose and eye symptoms) were assessed using a scale from 0 to 3 (0=none, 1=mild, 2=moderate and 3=severe). Global therapeutic response was assessed using a scale from 1 to 5 (1=complete relief, 2=marked relief, 3=moderate relief, 4=slight relief and 5=no relief/treatment failure). Adverse events were recorded.

**Results:** 660 Patients, aged 12-65 years (32.7 +/- 10.055), were enrolled. At baseline the mean total nasal symptom score (TNSS) was 7.82. At the end of treatment, 79.7% of treated patients were either very satisfied (33.79%) or extremely satisfied (45.91%) with the effect of DL on SAR symptoms at nighttime and early morning. DL produced significant reduction in TNSS (-6.01; P < 0.0001) as well as in each individual symptom score. Complete and marked relief was reported in 79.85% of patients. DL was well tolerated.

**Conclusion:** Once daily DL resulted in a high level of patient's satisfaction in controlling SAR symptoms at both nighttime and early morning in routine daily practice in Saudi Arabia.

### **Desloratadine significantly reduces total symptoms scores in subjects with intermittent allergic rhinitis: Results of the ACCEPT1 study in collaboration with GA<sup>2</sup>LEN**

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**Background:** Intermittent AR (IAR) is defined under the ARIA guidelines as allergic rhinitis (AR) symptoms for <4 days/week or for <4 consecutive weeks. Non-sedating antihistamines, such as desloratadine (DL), are 1st-line therapy for IAR and persistent AR. While DL is a safe and effective treatment for AR, it has not been studied prospectively in the setting of IAR.

**Methods:** This was a prospective, randomized, multi-center, multi-national, placebo-controlled, parallel-group study of the safety and efficacy of DL 5mg or Placebo QD for 15 days in subjects with IAR. To be eligible, subjects aged ≥12 yr had to have a diagnosis of AR for ≥2 yr that was consistent with IAR and have a positive skin-prick test to ≥1 prevalent/ GA<sup>2</sup>LEN panel allergens. Individual symptom scores were rated on a 4-point scale (0=none to 3=severe). The total 5-symptom score (T5SS) was the sum of scores for nasal congestion, sneezing, rhinorrhea, nasal pruritus and ocular pruritus. Subjects scored their symptom severities twice daily (AM/PM) in terms of current severity (NOW) and over the previous 12 hours (PRIOR). To be eligible, the sum of the average AM and PM PRIOR T5SS on days -4 to -1 plus the AM PRIOR T5SS on day 1 had to be ≥30. The primary efficacy endpoint was the change from baseline in the average AM/PM-PRIOR T5SS score averaged over days 1-15. Adverse events were classified by severity and relation to study treatment.

**Results:** A total of 547 subjects were randomized (DL=276, Placebo=271); the mean age was 34.2 yrs and 58% of subjects were female. A significantly greater decrease from baseline in the average AM/PM-PRIOR T5SS over days 1-15 was seen with DL vs. Placebo (-3.01 vs. -2.13; P<0.001). Significantly greater decreases in AM/PM-PRIOR T5SS with DL vs. Placebo occurred from Day 1 (P=0.001) and on all 15 days of the study (P≤0.013). The significant effect of DL on T5SS endured across the full 24hr dosing period (AM NOW T5SS) as early as the first full 24-hr measurement on Day 2 (P<0.001) and averaged over Days 2-15 (P<0.001). DL was well tolerated and had an adverse event profile similar to Placebo.

**Conclusion:** In this, the first prospective, placebo-controlled study of an antihistamine in subjects with ARIA-defined IAR, DL was well tolerated and significantly reduced the T5SS from baseline vs. Placebo. Significant reductions in AM/PM-PRIOR T5SS occurred as early as Day 1, and lasted for the full 24-hr dosing period across the entire study.

**Desloratadine significantly improves pharmacoeconomic outcome in subjects with intermittent allergic rhinitis: Results of the ACCEPT1 study in collaboration with GA<sup>2</sup> LEN**

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**Background:** Allergic rhinitis (AR) is a very common chronic disease worldwide and AR symptoms cause impaired quality of life and performance. Together, this leads to high indirect costs in terms of decreased work productivity. The impact of first-line treatments (e.g. desloratadine (DL)) on pharmacoeconomic outcomes in intermittent allergic rhinitis (IAR) has not been studied previously. Methods: This was a prospective, randomized, multi-center, multi-national, placebo-controlled, parallel-group study of the safety and efficacy of DL 5mg or Placebo QD for 15 days in subjects with IAR. Eligible subjects ( $\geq 12$  yrs) had a diagnosis of AR  $\geq 2$  yrs consistent with IAR and  $\geq 1$  positive prevalent or GA<sup>2</sup> LEN allergen panel skin-prick tests. The Work Productivity Activity Impairment-Allergy Specific (WPAI-AS) questionnaire was used to assess pharmacoeconomic aspects of treatment, and included specific ratings for time lost from work, impairment while working, time lost from school, impairment while in school and impairment of general daily activities. The WPAI-AS was administered at baseline, day 8 and at the study endpoint. Statistical analyses included assessment of mean changes in percent overall work impairment, percent overall impairment in the classroom, and percent activity impairment in the DL and Placebo groups.

**Results:** The DL (n=276) and Placebo (n=271) groups had similar baseline mean WPAI-AS domain scores. Subjects in the DL group had a significant reduction in percent overall work-related impairment as compared with Placebo (-15.0 (-24.7%) vs. -5.7 (-1.6%), respectively; P=0.002). Impairment while working ("presenteeism") was reduced to a significantly greater extent with DL versus Placebo (-13.2 (-20.3%) vs. -4.1 (3.5%), respectively; P=0.001). Significantly less impairment of accomplishing daily activities occurred among subjects in the DL group versus Placebo (-15.3 (-31.1%) vs. -9.2 (-17.9%), respectively; P=0.007). In the few subjects attending school (DL=46, Placebo=49) there was a positive trend (P=NS) favoring DL vs. Placebo in terms of lower overall impairment (-12.5 (-20.8%) vs. -2.5 (4.1%), respectively) and lower impairment in the classroom (-14.3 (-20.8%) vs. -5.0 (-1.3%), respectively).

**Conclusions:** This is the first prospective evidence showing that DL treatment for 15 days in subjects with ARIA-defined IAR was associated with a positive pharmacoeconomic outcome in terms of decreased impairment of work and activities.