902 Fluticasone Furoate* (FF) Nasal Spray-Ergonomic Considerations for a Next Generation Delivery System [*USAN approved name]

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RATIONALE: Delivery systems should be designed to be comfortable and easy to use.

METHODS: The FF device was designed from first principles for optimal ergonomics. Published data were reviewed to establish appropriate values for key dimensions and forces required to operate the device. Device concepts were modelled and evaluated by user groups with feedback used to refine and finalise the design. The device design intent included:

- Minimal number of steps for use
- Suitable for use by a wide patient population

The forces required to operate the device can be achieved by children and by the elderly.

- Easier third party administration

Administration by care givers to children or to patients unable to self-administer.

- Determining when to refill their medication

A window enables the patient to assess the level of medication remaining.

RESULTS: *In-vitro* tests confirmed that the device operates reliably when a force of 20-40N is applied to the side lever. A Phase III clinical study (n=302) determined that 84% of patients found the device easy to use. A review by an independent ergonomist concluded that the device is more comfortable to hold and easier to operate than currently marketed 'top-down' nasal spray devices and is suitable for use in patients 2 years of age and older.

CONCLUSIONS: The FF delivery system is easy to operate and requires only basic preparation. The novel, unique side-actuated device is a next generation in nasal spray technology.

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903 Once-Daily Fluticasone Furoate* Nasal Spray (FFNS) Improves Quality of Life (QoL) in Subjects with Seasonal Allergic Rhinitis (SAR) during the mountain cedar pollen season *USAN approved name

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RATIONALE: Patients with allergic rhinitis are often bothered by nasal symptoms as well as other associated symptoms such as headache and fatigue. This combination may significantly impact their QoL through impairment of day-to-day physical, occupational, and social functioning as well as possibly leading to emotional distress.

METHODS: The Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), a 28-item, self-administered, disease-specific QoL instrument was used to assess QoL changes in a randomized, double-blind, placebo-controlled, two-week trial of 302 SAR subjects (≥12 years) randomized to once-daily FFNS 110mcg or placebo spray during the mountain cedar pollen season. The RQLQ was administered at baseline and at end of study (Week 2/ early withdrawal). An RQLQ score reduction of at least 0.5 from baseline has been determined to be a clinically meaningful difference (CMD).

RESULTS: Least square mean change from baseline compared with placebo was statistically significant and clinically meaningful for the overall RQLQ score (-0.688, p<0.001). All domains of the RQLQ: Activities (-0.644, p=0.034), Sleep (-0.508, p=0.023), Non-hay fever symptoms (-0.574, p=0.006), Practical problems (-0.919, p<0.001), Nasal symptoms (-0.943, p<0.001), Eye symptoms (-0.743, p=0.001), and Emotional problems (-0.544, p=0.013) were also significantly different and met CMD compared with placebo.

CONCLUSIONS: During a two-week mountain cedar SAR study, subjects receiving FFNS 110mcg once-daily had significant and clinically meaningful improvements in their overall rhinitis related QoL, notably including improvements in eye and sleep related QoL issues, when compared with placebo.

904 Do Allergic Rhinitis (AR) Patients Achieve Twenty-four Hour Symptom Control?

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RATIONALE: The aim of treatment of AR is for patients to be symptom free twenty-four hours a day. However, few studies have addressed the achievement of this goal.

METHODS: A cross-sectional survey (DSP V Programme, Adelphi) was completed by AR patients attending primary care and specialist clinics in the US. Physicians were asked to complete a patient record form, which included questions on symptoms, on consecutive patients with AR. The patients were also asked to complete a record form, including questions on symptoms. The survey was conducted February-April 2006.

RESULTS: 295 matched records were completed by patients with Seasonal Allergic Rhinitis (SAR) or Perennial Allergic Rhinitis (PAR) and their physician. Nearly 100% of patients were prescribed treatment: 36.9% non-sedating antihistamine (NSA) and a nasal corticosteroid, 34.6% NSA only, 24.1% nasal corticosteroid only. Patients reported that they had been symptom free for a mean 16.04 (StDev 9.83) days in the past 4 weeks. Only 16.8% of patients reported all 28 days free of symptoms. Physicians considered that only 61.6% of their patients had well/ completely controlled AR in past 4 weeks. AR bothered patients all times of the day and during the night. Over half of the patients (55.6%) reported that AR bothered them immediately after waking with 43.1% having evening symptoms. Nearly one quarter (23.7%) of patients were bothered during the night.

CONCLUSIONS: These data indicate that many AR patients may not have optimally controlled disease. Despite being prescribed medication, they continue to suffer symptoms, often immediately on waking and in the evening.

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905 Buffered Hypertonic Saline Nasal Spray and Gel As Treatment Modifiers in Allergic and Vasomotor Rhinitis

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RATIONALE: To determine if the addition of a buffered hypertonic saline nasal spray (ENTSOL® Spray), with or without the application of a buffered hypertonic saline nasal gel (ENTSOL® Gel), in combination with intranasal triamcinolone acetonide improves the efficacy of treatment with intranasal steroids and diminishes adverse effects of patients placed on these regimens.

METHODS: Participants with allergic and/or vasomotor rhinitis were randomized to use either triamcinolone acetonide nasal spray alone or the combination therapy of triamcinolone acetonide plus ENTSOL® Spray for a six week study period. ENTSOL® Gel was given to those participants using monotherapy or the combination therapy who were experiencing nasal irritation after three weeks. Measurements of rhinitis were conducted by the investigators at baseline, after 3 and 6 weeks of treatment utilizing a symptom score scale.

RESULTS: We enrolled 103 male and female participants ages 19 to 82. We observed a significant reduction in septal irritation (P<.01) following treatment with buffered hypertonic saline nasal spray plus intranasal triamcinolone acetonide in comparison to the septal irritation following treatment with triamcinolone acetonide only. Patients treated with intranasal triamcinolone acetonide only who experienced significant septal irritation had a reversal of mucosal changes by the addition of hypertonic nasal spray and gel to the treatment regimen at week 3.

CONCLUSION: The beneficial effects seen in this six week study leads to the conclusion that the addition hypertonic saline spray with/without gel produces improved clinical effectiveness and minimized adverse effects, therefore allowing patients to obtain the maximal benefit from a daily regimen of intranasal steroid sprays.

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