These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert
For product information, please log-on to the web site www.nasacort.com or contact one of our Medical Information Specialists at (800) 633-1610.

Proprietary Drug Name: NASACORT® AQ Nasal Spray	**INN:** Triamcinolone Acetonide Nasal Spray	**Therapeutic area and FDA approved indications:** For the treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 6 years of age and older.
Name of Sponsor/Company:	Aventis Pharmaceuticals,Inc., Member of the sanofi-aventis group	

Title of Study: Evaluation of a Newly Developed Preference Questionnaire for Intranasal Corticosteroids in Patients with Allergic Rhinitis Treated with Nasacort® AQ (Triamcinolone Acetonide) Nasal Spray 220 mcg and Nasonex® (Mometasone Furoate) Nasal Spray 200 mcg – A Pilot Study

Principal Study Investigators:

1) Sandra Gawchik, D.O., 2) William C. Howland, III, M.D., 3) Eli Meltzer, M.D., 4) Gordon Raphael, M.D.

Study centre(s): 4 US sites

1) Chester, PA, 2) Austin, TX, 3) San Diego, CA, 4) Bethesda, MD.

Publication: Meltzer EO, Hadley J, Blaiss M, Benninger M, Kimel M, Kleinman L, Dupclay L,Garcia J, Leahy M, Georges G. Development of questionnaires to measure patient preferences for intranasal corticosteroids in patients with allergic rhinitis. *Otolaryngol Head Neck Surg*. 2005 Feb;132(2):197-207.

Study period (years): (date of first enrolment) (date of last completed) : From 9 September, 2002 to 23 September 2002.	**Phase of development:** Phase IV

Objectives:

Primary: To determine the standard deviation and discriminatory capability of a newly developed clinical trial patient preference questionnaire (CTPPQ) for intranasal corticosteroids in patients with allergic rhinitis.
Secondary: To determine if the study's questionnaire requires any modifications prior to conducting the instrument's validation clinical trial.

Methodology: Randomized, double-blind, single dose, cross-over study.

Number of patients (planned and analyzed): 48 patients enrolled and completed the study

Diagnosis and main criteria for inclusion: To be eligible for enrollment, patients were required to:

- be male or female age 18-70 years;
- have a two-year (or longer) history of allergic rhinitis;
- be symptomatic at study inclusion;
- have a positive skin test for at least one allergen that was positive in the patient's environment (documented historical testing performed during the past year was accepted);
- have no clinically significant abnormalities in a physical examination or medical conditions that would interfere with the study;
- have no deviated septum or gross deformities of the nose sufficient to impair normal breathing;
- have no current or history of hyposmia and/or anosmia
- have met the washout periods for rhinitis medications prior to randomization.

Test product, dose and mode of administration, batch number:

Nasacort® AQ, 220 µg once daily (2 nasal sprays / nostril qd). Lot number MN-4995

Duration of treatment: 1 day

Reference therapy, dose and mode of administration, batch number

Nasonex®, 200 µg once daily (2 nasal sprays / nostril qd). Lot number 2-KTL-106

Criteria for evaluation:

Efficacy:

The assessment of study drugs was done through the self-completed CTPPQ. The CTPPQ consisted of three domains: satisfaction, preference, and expected compliance, rated on Likert-type scales. Patients rated their "satisfaction" immediately after each drug had been administered. The "preference" and "expected compliance" questions were completed at the end of the study after both nasal sprays had been administered.

The "satisfaction" section of the CTPPQ asked patients to rate their satisfaction with the following 9 attributes: immediate taste of the medication, aftertaste of the medication, smell of the medication, irritation to the nose, urge to sneeze, dripping out of the nose, dripping down the throat, moistness of the nose or throat, and overall satisfaction. The patients rated each attribute according to the following scale: very dissatisfied, moderately dissatisfied, somewhat dissatisfied, neither satisfied or dissatisfied, somewhat satisfied, moderately satisfied, or very satisfied.

The "preference" section of the CTPPQ included the following items: immediate taste of the medication, aftertaste of the medication, smell of the medication, irritation to the nose, urge to sneeze, dripping out of the nose, dripping down the throat, moistness of the nose or throat, and overall preference. The patient rated his/her preference for each item according to the following scale: strongly prefer Medication "A", somewhat prefer Medication "A", slightly prefer Medication "A", no preference, slightly prefer Medication "B", somewhat prefer Medication "B", or strongly prefer Medication "B".

In the "expected compliance" section of the CTPPQ, the patient rated how likely he or she would take the first and second nasal spray medications over an extended period of time (e.g., several months), according to the following ratings: not likely to take, somewhat likely to take, moderately likely to take, or very likely to take.

Safety: Safety was assessed on the basis of clinical examination and adverse events.

Statistical methods:

Mean scores on the CTPPQ were summarized for each dosing group. Results were compared between the two nasal sprays using a t-test or analysis of variance for continuous data and a Cochran-Mantel-Haenszel test for non-continuous data.

Analysis was preformed on the intent-to-treat population, which included any patient who received at least one product.

SUMMARY – CONCLUSIONS

EFFICACY RESULTS: Patients indicated an overall preference (Overall Preference Score) for Nasacort® AQ over Nasonex® nasal spray [59.6% (28/47) vs. 29.8% (14/47), *P* = 0.0436]. However, no statistically significant differences between nasal sprays were identified for the Overall Satisfaction Score or the Expected Compliance Score.

Analysis of the individual mean patient satisfaction scores for all sensory attribute questions on the CTPPQ indicated that patients were more satisfied with Nasacort® AQ as compared to Nasonex® in terms of immediate taste (5.33 vs. 4.58, *P* = 0.0204) and smell (5.21 vs. 4.19, *P* = 0.0065). Similar results were obtained when the individual mean preference scores were analyzed, i.e., patients preferred the immediate taste [54.2% (26/48) vs. 20.8% (10/48), *P* = 0.0113] and smell [56.3% (27/48) vs. 25% (12/48), *P* = 0.0237] of Nasacort® AQ over Nasonex®.

The Pearson correlation coefficients between overall satisfaction and compliance, overall satisfaction and overall preference, compliance and overall preference were highly statistically significant (*P*<0.001). The overall satisfaction correlation with the individual questions on the CTPPQ were statistically significant for all the questions for Nasacort® AQ and Nasonex® as determined by Pearson correlation coefficients.

SAFETY RESULTS: Nasacort® AQ and Nasonex® were safe and well tolerated following a single administration at a dose of 220 mcg and 200 mcg, respectively. When interviewed regarding any AEs that occurred following each nasal spray administration, of all 48 patients enrolled, 4 (8.3%) patients reported 4 AEs following Nasacort® AQ administration, 3 (6.3%) patients reported 7 AEs following Nasonex® administration. All of the AEs reported during the study were of mild intensity and were related to the study medication.

There were no deaths during the study. No patient prematurely discontinued from the study due to an AE.

Date of the report: 28 March, 2003