# New Data Presented at ACAAI Informs on the Safety and Efficacy of Nasacort AQ Nasal Spray in a Trial of Children Aged 2-5 Years Old with Year-Round Allergic Rhinitis

## Data Also Showed That Over a 6 Month Period, Nasacort AQ Did Not Cause Significant Adrenal Suppression in This Same Age Group

Bridgewater, NJ-November 10, 2007— Data presented at the American College of Allergy, Asthma & Immunology (ACAAI) annual meeting suggests that the intranasal corticosteroid Nasacort AQ (triamcinolone acetonide) Nasal Spray may be used safely and effectively to treat children aged 2-5 years old with year-round allergic rhinitis. The same study also showed that during the study, Nasacort AQ did not show a significant effect on adrenal function among a subset of the same patients.

Caused by an allergic reaction to allergens such as house dust, animal dander, or pollen, allergic rhinitis is the most common chronic childhood disease, effecting as many as 40% of all children in the U.S.

**A clinical study suggests that Nasacort AQ may present a safe and effective treatment option in children aged 2-5 years with year-round allergic rhinitis**

In a multicenter, randomized, double-blind study, Nasacort AQ, given as 1 spray per nostril once daily for 4 weeks, improved combined symptoms of sneezing, nasal itching, discharge, and congestion, compared with placebo in children aged 2-5 years who have had year-round allergic rhinitis for at least one year. Nasacort AQ also showed comparable safety to placebo.

“This study suggests that Nasacort AQ may be used safely and effectively to treat young children who suffer from year-round allergies, “said lead investigator Dr. Steven Weinstein of University of California at Irvine College of Medicine.

This study is the first and only randomized, double-blind, placebo-controlled study designed specifically to investigate both the efficacy and safety of an intranasal corticosteroid in this very young age group. A total of 474 patients were randomized to receive either Nasacort AQ or placebo as 1 spray per nostril once daily for 4 weeks. To participate in the study, patients had to have year-round allergic rhinitis for at least one year and

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reported sufficiently severe symptoms of nasal stuffiness, discharge and sneezing. Also, all patients had to demonstrate sensitivity to such allergens in their system as shown by a positive skin prick test.

Every morning, caregivers were asked to rate his/her child's symptoms of sneezing, nasal stuffiness, discharge, and itching over the last 24 hours (reflective). Patients' symptoms were also rated at the time immediately before receiving their daily medication (instantaneous).

Over four weeks, patients treated with Nasacort AQ showed a statistically significant (P=0.0328) reduction in the combined symptoms of sneezing, nasal stuffiness, discharge and itching (Total Symptom Score or TSS) measured over the last 24 (-2.31±0.15) compared to placebo (-1.87±.151). Immediately before receiving the daily treatment, patients treated with Nasacort AQ also reported a numeric, albeit not statistically significant (P= 0.0946), reduction (-2.28±0.16) in TSS compared to placebo (-1.92±.16).

Side effects among patients treated with Nasacort AQ were similar to those given placebo and no serious adverse events or clinically meaningful changes in vital signs were reported in either group. Side effects associated with treatment occurred in 50.8% of patients receiving Nasacort AQ and 48.3% of subjects receiving placebo. The most common treatment-related adverse events during the 4-week of treatment with Nasacort AQ and placebo respectively were cough (7.6%, 9.2%), pyrexia (fever) (6.8%, 8%), headache (5.5%, 4.2%), and nasopharyngitis (nose & throat irritation) (5.1%, 3.8%).

**In a subset of the same clinical study, Nasacort AQ showed no significant effect on average adrenal function in children aged 2-5 years with year-round allergic rhinitis**

Also presented at ACAAI is a report on the effect of Nasacort AQ on adrenal function from a subset of patients who participated in the same study described above. Adrenal function is responsible for many body processes such as response to stress, metabolism, the immune system, and sexual development and function.

Results reported by Dr. Nayak showed that 4 weeks of Nasacort AQ, given as 1 spray in each nostril once daily, did not significantly affect the average blood levels of the adrenal hormone "cortisol" compared with placebo among children 2-5 years with year-round allergic rhinitis.

"Traditionally there has been a concern regarding potential effects of the widely-used intranasal corticosteroids on adrenal function in children," said lead investigator Dr. Anjuli Nayak, University of Illinois College of Medicine. "We are encouraged by the results of this study which showed that during the 6 month study, Nasacort AQ did not cause significant adrenal suppression in children aged 2-5 years who suffer from year-round allergies."

Adrenal function was assessed in a subset of 61 children aged 2-5 years with PAR who received Nasacort AQ (n=33) or placebo (n=28) in the 4-week double-blind treatment phase; and in a subset of 49 children who continued on in a 6-month long open label extension period receiving Nasacort AQ once daily. To participate, patients had year-round allergic rhinitis for one year or longer and a positive skin prick test for allergens. Also, upon entering the study, patients needed normal morning cortisol levels. Cortisol measurements were conducted before and after adrenal stimulation with 1 mcg of cosyntropin hormone. A reduction in cortisol levels while receiving an intranasal corticosteroid treatment may signal adrenal suppression.

The patients' blood cortisol levels after cosyntropin are reported before and after the 4 weeks and 6 months of treatment. After four weeks, there was no significant reduction from baseline in the average level of morning cortisol in patients treated with Nasacort AQ (-29.60±42.73 nmol/L; *P*=0.49), or placebo (-35.50±43.73; *P*=0.42). Similarly, after 6 months, patients treated with Nasacort AQ, showed no significant reduction from baseline in their average morning cortisol levels (-53.34±40.13 nmol/L; *P*=0.1900).

**About Allergic Rhinitis**

Allergic rhinitis is a swelling of the nasal passages, usually accompanied by sneezing, watery nasal discharge and itching of the nose and eyes. This medical condition is caused by an allergic reaction to allergens such as house dust, animal dander, or pollen. On any given day, 10,000 American children miss school because of allergic rhinitis, for a total of 2 million lost school days.

**About Nasacort AQ**

Nasacort AQ Nasal Spray is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 6 years of age and older.

The most commonly reported side effects with Nasacort AQ Nasal Spray were similar to vehicle placebo. In adults and children ages 12 and older, they were: pharyngitis 5.1% vs 3.6%, epistaxis 2.7% vs 0.8%, and increase in cough 2.1% vs 1.5%. In studies including children ages 6 to 11, they were: pharyngitis 7.4% vs 6.4%, increase in cough 7.0% vs 6.4%.

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