

FDA Approves Nasacort AQ[®] Nasal Spray for Children Aged 2-5 years old

Randomized, double-blind, placebo-controlled study conducted in the U.S. demonstrated both the efficacy and safety of Nasacort AQ[®] in children with nasal symptoms associated with perennial allergic rhinitis

Paris, France - September 23, 2008— Sanofi-aventis announced today the U.S. Food and Drug Administration (FDA) has approved Nasacort AQ Nasal Spray (triamcinolone acetonide) for children aged 2-5 years old for the treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis.

The FDA based its approval on the results of a multicenter, randomized, double-blind, placebo-controlled study demonstrating that Nasacort AQ can be used safely and effectively to treat nasal symptoms of year-round allergies in children between two and five years. This is the first and largest placebo-controlled trial designed to specifically investigate both the efficacy and safety of an intranasal corticosteroid vs. placebo in 2-5 years of age group.

“We welcome this new treatment option for our very young patients,” said lead investigator Dr. Steven Weinstein, Director, Allergy and Asthma Specialist Medical Group in Huntington Beach, California. *“Nasacort AQ Nasal Spray has been proven effective for the age groups two to five years to relieve nasal allergy symptoms.”*

Approval Based on Pediatric Clinical Trial

The study showed that Nasacort AQ, given as 1 spray/ nostril once daily for four weeks to children aged 2-5 years, with year-round allergic rhinitis diagnosed for at least one year, significantly improved the combined symptoms of sneezing, itching, runny nose and congestion, compared with placebo.

A total of 464 patients were randomized and received 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 diagnosed for at least one year and reported sufficiently severe symptoms of nasal stuffiness, discharge and sneezing.

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

Over four weeks, patients treated with Nasacort AQ showed a reduction from baseline in the mean adjusted sum of symptoms including sneezing, nasal stuffiness, discharge and itching (Total Nasal Symptom Score or TNSS) measured over the last 24 hours (reflective TNSS) and immediately prior to dosing (instantaneous TNSS). Instantaneous TNSS was the primary end point and showed a greater reduction from baseline of -2.28 +/- 0.16 and -1.92 +/- 0.16 in the Nasacort AQ and placebo groups respectively trending in favor of Nasacort AQ (p value 0.095). Reflective TNSS showed a statistically significantly greater reduction from baseline in the Nasacort AQ group -2.31 +/- 0.15 vs. placebo -1.87



+/- 0.15 (p value 0.0328). The rates of the treatment-emergent adverse events (TEAEs) among patents treated with Nasacort were comparable to those given placebo (50.8% and 48.3% respectively). The most common TEAEs observed during the double-blind portion of the trial included cough (7.6% vs 9.2%), pyrexia (6.8% vs 8.0%), and headache (5.5% vs 4.2%) in the Nasacort AQ vs placebo groups respectively. No serious side effects were reported in either group. There were no clinically meaningful changes in any of the vital signs analyzed.

About Allergic Rhinitis

Allergic rhinitis is an allergic condition usually accompanied by sneezing, watery nasal discharge and itching of the nose and eyes. Caused by an allergic reaction to allergens such as house dust mites, animal dander, tree or grass pollen, allergic rhinitis is the most common chronic childhood disease, affecting as many as 40% of all children in the U.S. On any given day, 10,000 American children miss school because of allergic rhinitis, for a total of 2 million lost school days.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT PARIS: SAN) and in New York (NYSE: SNY).

Forward-looking statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2007. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts

Global: Richard Vento, sanofi-aventis, +33 1 53 77 43 18, richard.vento@sanofi-aventis.com

US: Amy Ba, sanofi-aventis, (908)-981-6563, amy.ba@sanofi-aventis.com