

FOR IMMEDIATE RELEASE

New treatment available in Canada for children with seasonal allergies and for adolescents and adults suffering from year round allergies

AVAMYS™ is the first intranasal steroid available in Canada indicated for the relief of allergic rhinitis and its associated symptoms affecting both the eyes and nose in adults and adolescents

Mississauga, ON (June 25, 2008) – GlaxoSmithKline Inc. announced today that AVAMYS™ (fluticasone furoate nasal spray) is available for the treatment of seasonal allergic rhinitis in children as young as two years of age as well as perennial (year-round indoor) allergic rhinitis and its associated symptoms in adults and adolescents (12 years and up).

AVAMYS is the only intranasal steroid (INS) indicated for use in children as young as two with seasonal allergic rhinitis in Canada.

AVAMYS is the first intranasal steroid available in Canada to be labeled for the relief of associated symptoms of allergic rhinitis affecting both the eyes and nose in adults and adolescents. It has shown statistically significant improvement in relieving overall eye symptoms such as itchy, burning and watery eyes in allergic rhinitis patients, 12 years of age and older, in five prospectively designed studies. Like nasal symptoms, ocular symptom relief lasted a full 24 hours.¹

AVAMYS is in part, a Canadian innovation. Certain stages of the medication's development were completed by scientists working at GlaxoSmithKline's Mississauga, Ontario site.

"Allergic rhinitis is an absolutely treatable condition so there's no reason people should sneeze, feel blocked and itch their way through the allergy season or for some people all year round" says Dr. Paul Keith, Associate Professor in the Division of Allergy and Clinical Immunology, Department of Medicine, McMaster University. "AVAMYS is the first prescription intranasal corticosteroid spray to have repeatedly and statistically demonstrated an improvement in the relief of both itchy, watery eyes and nasal congestion. This may offer appropriate allergy patients the convenience of a single once-daily treatment to relieve both their eye and nose symptoms."

The Delivery Device

The AVAMYS drug delivery device was designed and developed with patients in mind. AVAMYS has a novel side-actuated "mist release" button to make it easier to use by the patient or their caregiver. It delivers a gentle, scent and taste-free mist with a low volume of spray, which means patients are less likely to experience a bitter taste or the effects of drip down the back of the throat. The device has a small nozzle, designed to increase

comfort and fit more easily into the nose and a viewing window allows patients to see how much medicine is left in the device.

Clinical Trials

The approval of AVAMYS for the treatment of perennial or year round allergic rhinitis in adults and adolescents 12 years of age and over was based on clinical trials involving 604 patients. The studies evaluated a broad spectrum of perennial allergens (e.g. animal dander, house dust mites, cockroaches, and mould) known to trigger perennial allergic rhinitis.¹ In these studies, AVAMYS sustained its effectiveness for a full 24 hours (after a dose of AVAMYS).¹

The approval of AVAMYS in children with seasonal allergies was based on a phase III study involving 554 children 2 to 11 years of age. Administered once daily, AVAMYS effectively treated overall nasal symptoms, which included congestion, sneezing, itchy nose and runny nose.

In general, patients who took AVAMYS in the clinical trials (of 2 to 12 weeks) reported adverse reactions with approximately the same frequency as those who received placebo. The most common adverse reactions included nose bleed and nasal sores. Other effects experienced by patients in these clinical trials with AVAMYS included headache, sore throat, and back pain. In general, adverse reactions seen with AVAMYS were similar to those seen with other intranasal steroids and were primarily associated with irritation of the nasal membranes.^{1,2,3}

Quality of Life Endpoints

Adult and adolescent perennial allergic rhinitis patients taking AVAMYS also reported statistically significant and clinically meaningful improvements in the overall rhinitis-specific quality of life score [as measured by the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ)] compared with placebo. Overall RQLQ score assesses the impact of allergic rhinitis treatment on seven domains: activities, sleep, non-nose/eye symptoms, practical problems, nasal symptoms, eye symptoms and emotional problems.^{1,2,4}

About Allergic Rhinitis

Allergic rhinitis, known as nasal allergies, is an inflammatory reaction of the nasal passages to allergens, such as pollens, dust mites, animal dander, and mold spores. One of the most prevalent and chronic diseases in Canada, nasal allergies affect up to 6 million people, including 20 to 25 per cent of adults and up to 40 per cent of children. Within minutes of exposure to an allergen, immune response cells release chemicals such as histamine and leukotrienes that lead to inflammation and may produce symptoms including nasal congestion, sneezing and runny or itchy nose.

Seasonal allergic rhinitis, triggered by pollens, occurs during certain seasons and lasts a few weeks to a few months. Perennial allergic rhinitis, triggered by dust mites, animal dander and mold, occurs year-round.

Seasonal allergy signals in children include the “allergic salute” and “allergic shiners”. The “allergic salute” is a common habit of children which consists of rubbing their nose upward. This is because the nose is itchy and it can cause a crease in the skin of the lower part of the nose. Children with seasonal allergic rhinitis also commonly have “allergic shiners”, which are dark circles under the eyes caused by nasal congestion.

About GlaxoSmithKline

GlaxoSmithKline – one of the world’s leading research-based pharmaceutical and health-care companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. In Canada, GlaxoSmithKline is among the top 15 investors in research and development, contributing more than \$176 million in 2006 alone. GSK is an Imagine Caring Company, and is consistently recognized as one of the 50 Best Employers in Canada. For company information, please visit www.gsk.ca

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¹ Avamys Product Monograph.

² Fokkens WJ et al. Once daily fluticasone furoate nasal spray is effective in seasonal allergic rhinitis caused by grass pollen. *Allergy* 2007; 62: 1078-1084.

³ Kaiser H et al. Once-daily fluticasone furoate nasal spray (FFNS) is effective for the treatment of Seasonal Allergic Rhinitis (SAR) caused by Ragweed. Presented at the AAAAI 2007. Data on file.

⁴ Given J, Toler T, Ellsworth A, Stanford R, Philpot E. Once-Daily Fluticasone Furoate Nasal Spray 110mcg Improves Quality of Life (QoL) in Subjects with Seasonal Allergic Rhinitis (SAR) during the ragweed season. Presented at AAAAI 2007. Data on file.