

FDA Approves Xyzal (levocetirizine dihydrochloride) Oral Solution for the Relief of Seasonal and Year Round Allergies and Chronic Idiopathic Urticaria

BRUSSELS, BELGIUM, February 19 / MARKET WIRE

Brussels, Belgium and Paris, France - February 19, 2008 at 8:00 am CET - UCB and Sanofi-Aventis announced today that the U.S. Food and Drug Administration (FDA) approved a New Drug Application (NDA) for XYZAL® (levocetirizine dihydrochloride) 0.5 mg/mL oral solution, a prescription antihistamine indicated for the relief of symptoms associated with indoor and outdoor allergies, as well as the treatment of chronic idiopathic urticaria. XYZAL® tablets received FDA approval on May 25, 2007 and both formulations are now approved for use in adults and children 6 years and older.

"The oral solution of XYZAL® provides a welcome alternative for those patients who have difficulty swallowing or who prefer liquid medication," said Michael S. Blaiss, MD, Clinical Professor of Pediatrics and Medicine at the University of Tennessee Health Science Center in Memphis, Tennessee. "Both the oral solution and tablets offer patients powerful and long-lasting allergy relief."

Studies in allergic rhinitis patients demonstrated levocetirizine significantly reduced the symptoms of sneezing, itchy nose, runny nose, and itchy eyes. Studies in chronic idiopathic urticaria patients showed levocetirizine significantly reduced the severity of itching and the number and size of wheals.

In September 2006, UCB and sanofi-aventis entered into an agreement to launch and co-market XYZAL® in the U.S. UCB and sanofi-aventis have a long history in the allergy treatment arena and are committed to advancing treatment for allergy sufferers and helping meet unmet medical needs for patients with chronic allergy symptoms.

About Allergic Conditions

Many people suffer from the symptoms associated with common allergic conditions. The immune system of allergy sufferers over-reacts to something in the environment, leading to symptoms that affect their respiratory system, eyes, or skin. Estimates from the American Academy of Allergy, Asthma & Immunology (AAAAI) suggest that indoor and outdoor allergies affect as many as 40 million people in the United States.

Seasonal allergic rhinitis (SAR), commonly referred to as "hay fever" or "outdoor allergies," is the most common form of allergic rhinitis. By definition, SAR includes allergies to seasonal pollens like grass, trees, and weeds, as well as mold. Perennial Allergic Rhinitis (PAR) is sometimes referred to as "year round" or "indoor allergies" and is characterized by allergic symptoms that last longer than four weeks. House dust mites, animal dander, and mold most commonly trigger PAR. Chronic Idiopathic Urticaria (CIU) is most commonly known as "chronic hives of unknown origin" and is defined as the occurrence of daily, or almost daily, wheals and itching for at least six weeks with no obvious causes.

About XYZAL®

Indications and Important Safety Information XYZAL® is indicated for the relief of symptoms associated with allergic rhinitis (seasonal and perennial) and the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

The use of XYZAL® is contraindicated in: patients with a known hypersensitivity to levocetirizine or any of the ingredients of XYZAL or to cetirizine (observed reactions range from urticaria to anaphylaxis); patients with end-stage renal impairment at less than 10 mL/min creatinine clearance or patients undergoing hemodialysis; and pediatric patients aged 6 to 11 years with impaired renal function.

Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness and motor coordination, such as operating machinery or driving a motor vehicle, after ingestion of XYZAL®. Concurrent use of XYZAL® with alcohol or other central nervous system (CNS) depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur.

In clinical trials, the most common adverse reactions in $\geq 2\%$ of adult and adolescent patients (12 years of age and older) taking XYZAL 2.5 mg, XYZAL® 5 mg, or placebo were somnolence (5%, 6%, 2%), nasopharyngitis (6%, 4%, 3%), fatigue (1%, 4%, 2%), dry mouth (3%, 2%, 1%), and pharyngitis (2%, 1%, 1%), respectively.

In clinical trials 4 to 6 weeks in duration, the most common adverse reactions in $> 2\%$ of pediatric patients (6-12 years of age) taking XYZAL® 5 mg included pyrexia (4% vs 2% placebo), cough (3% vs $< 1\%$ placebo), somnolence (3% vs $< 1\%$ placebo) and epistaxis (2% vs $< 1\%$ placebo).

Full prescribing information for XYZAL® is available at www.XYZAL.com.