



**Contacts:**

**UCB**

**Jean-Christophe Donck**  
+32 2 559-9346  
jc.donck@ucb-group.com

**sanofi-aventis**

**Salah Mahyaoui**  
+ 33 6 73.68.78.88  
salah.mahyaoui@sanofi-aventis.com  
**Richard Vento**  
+ 33 6 78.79.93.26  
richard.vento@sanofi-aventis.com

**FDA approves XYZAL<sup>®</sup> tablets for the treatment of seasonal and year round allergies, and chronic urticaria**

***-New once-daily prescription antihistamine for rapid and long-lasting symptomatic relief to millions of allergy sufferers-***

**Brussels (Belgium) and Paris (France), May 29, 2007** – UCB and sanofi-aventis announced today that the U.S. Food and Drug Administration (FDA) has approved XYZAL<sup>®</sup> (levocetirizine dihydrochloride), a new once-daily prescription antihistamine that delivers a rapid and long-lasting effect for the relief of symptoms associated with seasonal and perennial allergic rhinitis and treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children six years of age and older.

*“With allergies on the rise and longer-lasting allergy seasons, patients desire a fast and long-acting treatment,”* said Michael S. Blaiss, MD, Clinical Professor of Pediatrics and Medicine at the University of Tennessee Health Science Center in Memphis, Tennessee. *“XYZAL<sup>®</sup> is a new treatment option in today’s more challenging allergy environment.”*

UCB filed the new drug application (NDA) with FDA in July 2006 and has extensively researched XYZAL<sup>®</sup> in numerous clinical trials. Studies in allergic rhinitis patients demonstrated XYZAL<sup>®</sup> significantly reduced the symptoms of sneezing, itchy nose, runny nose, and itchy eyes. Studies in chronic idiopathic urticaria patients showed XYZAL<sup>®</sup> 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<sup>®</sup> 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. XYZAL<sup>®</sup> once-daily tablets are expected to be available during the 2007 fall allergy season.

*“I am very pleased to have sanofi-aventis as our partner in bringing XYZAL<sup>®</sup> to the U.S. market,”* said UCB’s U.S. President, Fabrice Egros. *“The approval of XYZAL<sup>®</sup> will offer an alternative for U.S. physicians seeking a new prescription treatment option for patients. We*

*are confident that the attributes of XYZAL<sup>®</sup>, along with our dedicated selling efforts, will result in the successful launch of this drug in the U.S."*

*"We are excited about the FDA approval of XYZAL<sup>®</sup> and our partnership with UCB," said Brent Ragans, Vice President, Specialty Markets, sanofi-aventis. "Building upon our long history in the allergy treatment arena, this opportunity allows us to continue our leadership position in this field and demonstrate our commitment to providing treatment advances for the millions of allergy sufferers in the U.S."*

### **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 College of Allergy, Asthma & Immunology (ACAAI) suggest that allergies affect as many as 40 to 50 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 "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<sup>®</sup>**

Indications and Important Safety Information:

XYZAL<sup>®</sup> 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.

In clinical trials, the most common adverse reactions in  $\geq 2\%$  of adult and adolescent patients (12 years and older) taking XYZAL<sup>®</sup> 5 mg were mild to moderate in intensity and included somnolence (6% vs. 2% placebo), nasopharyngitis (4% vs. 3% placebo), fatigue (4% vs. 2% placebo) and dry mouth (2% vs. 1% placebo). The most common adverse reactions in  $\geq 2\%$  of pediatric patients (6-12 years of age) taking XYZAL<sup>®</sup> 5 mg included pyrexia (4% vs. 2% placebo), cough (3% vs. <1% placebo), somnolence (3% vs. <1% placebo), and epistaxis (2% vs. <1% placebo).

The use of XYZAL<sup>®</sup> is contraindicated in patients with end-stage renal disease (CLcr <10 mL/min) and in patients undergoing hemodialysis. XYZAL<sup>®</sup> is also contraindicated in 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<sup>®</sup>. Concurrent use of XYZAL<sup>®</sup> with alcohol or other central nervous system depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur.

XYZAL<sup>®</sup> was first launched in Europe in 2001 and is currently marketed in over 80 countries around the world. The FDA approval is based primarily upon the results of eight randomized, placebo-controlled clinical trials involving over 2,000 patients.

## **About UCB**

UCB ([www.ucb-group.com](http://www.ucb-group.com)) is a leading global biopharmaceutical company dedicated to the research, development and commercialization of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB focuses on securing a leading position in severe disease categories. Employing over 8,500 people in over 40 countries, UCB achieved revenue of 2.5 billion euro in 2006. UCB is listed on the Euronext Brussels Exchange. Worldwide headquarters are located in Brussels, Belgium.

## **About sanofi-aventis**

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

## **UCB Forward-Looking Statement**

*This news release contains forward-looking statements that involve risks and uncertainties, including statements with respect to the development and commercialization of levocetirizine. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: the results of research, development and clinical trials; the timing and success of submission, acceptance, and approval of regulatory filings; the time and resources UCB devotes to the development and commercialization of levocetirizine and the scope of UCB's patents and the patents of others.*

## **Sanofi-aventis 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, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*