FDA Approves Once-Daily Cipro® XR for the Treatment of Uncomplicated Urinary Tract Infections (UTIs)

Uncomplicated UTIs Result in More Than 8 Million Doctor Visits Annually; Extended Release Formulation Provides Once-a-Day Dosing For Patients

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WEST HAVEN, CT, December 16, 2002 – Bayer Corporation announced today that the U.S. Food and Drug Administration (FDA) has approved Cipro® XR (ciprofloxacin* extended-release tablets), a new formulation of ciprofloxacin, given once-a-day over three days, for the treatment of uncomplicated urinary tract infections (UTIs) due to susceptible strains of indicated organisms. Cipro XR will be marketed for use at a dosage strength of 500 mg.

Cipro XR was developed using a bilayer matrix of the active ingredient ciprofloxacin, and enables two different release mechanisms. The first is a rapid release of ciprofloxacin, which distributes to the serum and tissues within hours. This is followed by a second extended release of the active ingredient to allow sustained levels over 24 hours.

"This is good news for patients diagnosed with uncomplicated UTIs," said Dr. Thomas Hooton, Professor, Division of Allergy and Infectious Diseases, School of Medicine, University of Washington. "Once-daily dosing may enhance patient compliance, which can be an important factor in helping to achieve better outcomes as it is often easier to remember to take one pill rather than two."

Results of a prospective, randomized, double-blinded study were included in the New Drug Application (NDA) submitted to the FDA in March 2002. The study evaluated the treatment of 891 adult women with clinical signs and symptoms of acute uncomplicated UTI, including pyuria, and a positive pre-therapy urine culture. The primary endpoint of the study, which compared 500 mg Cipro® XR, given once-daily over three days, to the conventional twice-daily dose (250 mg) of Cipro® (ciprofloxacin HCl), was to demonstrate that treatment with Cipro XR was not inferior to treatment with Cipro. Results showed that Cipro XR is comparable in safety and efficacy to the conventional twice-daily dose of Cipro. The treatment groups were similar with respect to demographics and infection characteristics. Of the total treatment group, 444 were treated with Cipro XR; 447 were treated with Cipro.

According to Dr. Lawrence Posner, Senior Vice President and Worldwide Head, Regulatory Affairs, Bayer Corporation, "This study showed that Cipro XR was as effective and well-tolerated as twice-daily Cipro for the treatment of uncomplicated UTIs. This approval provides patients with a new and more convenient option for appropriate and targeted treatment."

Bayer Corporation submitted a NDA to the FDA in October 2002 to market once daily Cipro XR at a different dosage strength for the treatment of complicated UTIs.

Bayer will begin shipping Cipro XR 500mg to pharmacies on January 2, 2003.

About the Study

At the first assessment point, 4-11 days post-treatment, bacteriologic eradication was achieved in 94% in the once daily therapy arm and 94% in the twice a day-treated patients; clinical cure was observed in 95% of the once-daily treated patients compared to 93% of twice-daily therapy patients. Eradication of *E. coli*, the most predominant organism, was 97% for each group. These rates were consistent with those that investigators observed in the late treatment follow-up (25-50 days post-therapy). Drug related adverse events were similar for each group and included nausea, headache, and vaginitis.

About Uncomplicated Urinary Tract Infections (UTIs)

UTIs pose a potentially serious health problem that affects millions of people each year. Infections of the urinary tract are very common – only respiratory infections occur more frequently, according to the National Institutes of Health. Uncomplicated UTIs account for more than 8 million doctor visits annually. Women are especially prone to UTIs and their risk increases with age.

An uncomplicated UTI is usually a bladder infection that is caused by bacteria that enter the urethra and travel up the urinary tract. Patients who have an uncomplicated UTI generally do not have structural problems or obstructions within the urinary tract. Left untreated, the bacteria can spread and the condition can become more serious. UTIs can also be referred to as acute uncomplicated cystitis or bladder infections.

Indications and Important Safety Information

CIPRO XR is indicated solely for the treatment of uncomplicated urinary tract infections (acute cystitis) caused by Escherichia coli, Proteus mirabilis, Enterococcus faecalis, or Staphylococcus saprophyticus.

Serious and fatal reactions have been reported in patients receiving concurrent administration of ciprofloxacin and theophylline. Monitor theophylline levels if concurrent administration cannot be avoided.

The safety and effectiveness of ciprofloxacin in children, adolescents less than 18 years of age, pregnant women and lactating women have not been established. Ciprofloxacin is contraindicated in persons with a history of hypersensitivity to ciprofloxacin or any member of the quinolone class of antimicrobial agents. Ciprofloxacin should be discontinued at the first sign of an allergic reaction.

Adverse events determined to be at least possibly drug related occurring in ≥ 1% of patients were headache (2%) and nausea (3%).

Antacids containing magnesium, aluminum or calcium, or other products containing metal cations, should be taken 2 hours before or 6 hours after oral administration of Cipro XR.

Full prescribing information for CIPRO XR can be viewed at http://www.ciproxr.com

About Bayer Corporation

Best known for its flagship product, Bayer Aspirin, Bayer Corporation produces a broad range of healthcare, crop protection, polymer and chemical products that help diagnose and treat diseases, purify water, preserve local landmarks, protect crops, advance automobile safety and durability and improve people's lives.

Bayer Pharmaceuticals is a division of Bayer Health Care and a member of the worldwide Bayer Group, a $27 billion international healthcare and chemicals group based in Leverkusen, Germany. The Bayer Group stock is a component of the DAX and is listed on the New York Stock Exchange (ticker symbol: BAY).

* As ciprofloxacin† and ciprofloxacin hydrochloride† does not comply with the loss on drying test and residue on ignition test of the USP monograph.

Forward-Looking Statements

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F).The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.