

## **Bayer Submits Additional New Drug Application For Once-Daily Cipro<sup>®</sup> XR in US**

An Extended-Release Formulation for Complicated Urinary Tract Infections

**Leverkusen / West Haven (USA)** – Bayer Corporation, Pharmaceutical Division, a member of the worldwide Bayer Group based in Leverkusen, Germany, today announced it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) to market Cipro<sup>®</sup> XR (ciprofloxacin extended-release) in a once-daily modified release tablet formulation for the treatment of complicated urinary tract infections (UTIs). This new formulation of ciprofloxacin has been submitted for once-daily dosing for a course of 7-14 days.

Cipro XR was developed using a bilayer matrix of the active ingredient ciprofloxacin. This new formulation enables an initial 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 over 24 hours. In March 2002, Bayer submitted an NDA to the Food and Drug Administration to market Cipro XR (ciprofloxacin extended-release tablets) as a once-daily, three-day treatment for uncomplicated urinary tract infections.

“This NDA submission for Cipro XR in complicated urinary tract infections represents Bayer’s commitment to developing and bringing to market innovative therapies,” said Dr. Lawrence Posner, Senior Vice President and Worldwide Head, Regulatory Affairs, Bayer Corporation. “We asked physicians what was most important to their UTI patients and once-a-day dosing was a common response,” he added.

Urinary tract infections are a serious health problem, accounting for millions of physician visits each year. UTIs are most often caused by bacteria and are frequently treated with antibiotics, such as fluoroquinolones.

Complicated urinary tract infection (UTI) can be defined as symptomatic infection with significant bacteria in the urine associated with structural or functional urinary tract abnormality. Such abnormalities or risk factors predisposing patients to UTIs are numerous, including stones, neurogenic bladder disorder, urinary tract

instrumentation, catheterization, and metabolic conditions such as diabetes. Complicated UTI is often associated with recurrent infections and frequently involves multi-resistant microorganisms and can be associated with increased morbidity, mortality and length of stay in hospitalized patients.

Symptoms of UTIs include painful, burning urination, pelvic pain and the frequent urge to urinate. A physician can make a diagnosis of a UTI with a simple urine test for bacteria and pus. Left untreated, UTIs may lead to a more serious infection.

Leverkusen, Oktober 30, 2002

#### **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.