New Drug Application Filed for Intravenous Formulation of the Antibiotic Moxifloxacin in Treating Community-Acquired Respiratory Tract Infections

Bayer seeks Approval for IV Form of Fast-growing Oral Respiratory Antibiotic to Expand Treatment Options in the Hospital

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West Haven, Connecticut, November 6, 2000 – Bayer Corporation announced today that it has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for the intravenous (IV) form of the antibiotic moxifloxacin. The company is seeking marketing approval of moxifloxacin IV for use in the treatment of common adult community-acquired respiratory tract infections. Among the indications being sought is the indication for community-acquired pneumonia (CAP) caused by *Streptococcus pneumoniae (including penicillin-resistant strains), Haemophilus influenzae, Moraxella catarrhalis, Staphylococcus aureus, Klebsiella pneumonia, Mycoplasma pneumoniae, Chlamydia pneumoniae,* or *Legionella pneumophila.*

"If approved, the IV form of moxifloxacin would provide physicians with an important new option for treating more seriously ill patients in the hospital" said Lawrence Posner, MD, Head of Global Regulatory Affairs for Bayer. "The IV dose of moxifloxacin recommended in the NDA – 400 mg – is the same as the currently approved oral dose, and would allow an easy conversion from IV to oral therapy for potential hospital cost savings or to simplify continuing therapy when patients leave the hospital."

NDA Studies and Data for Moxifloxacin IV

The moxifloxacin IV NDA included data from two multicenter studies involving more than 1,100 patients hospitalized with CAP. One study included 516 patients from 89 centers in the United States and 15 in Canada; the other study included 628 patients from 65 treatment centers in Europe, Israel and South Africa.

These studies compared the effect of moxifloxacin IV 400 mg to either a fluoroquinolone or a beta-lactam with or without a macrolide. In both studies,

physicians initiated all patients on IV therapy, but then had the option to switch patients to oral therapy after 3 days.

Additional studies with both IV and oral formulations of moxifloxacin are underway in the hospital setting for the treatment of patients with hospital-acquired pneumonia, intra-abdominal infections or complicated skin infections.

About Moxifloxacin

Moxifloxacin IV is an intravenous formulation of the oral antibiotic moxifloxacin hydrochloride. Moxifloxacin HCl tablets are approved for use in 45 countries. Bayer Corporation distributes the tablets in the U.S. under the trade name AVELOX.

In the US, AVELOX tablets are currently approved for the treatment of common adult respiratory tract infections, including acute bacterial exacerbations of chronic bronchitis (ABECB)[1], acute bacterial sinusitis[2], and community-acquired pneumonia (CAP) of mild to moderate severity[3], caused by indicated susceptible organisms.

To date, there have been over 2.5 million patient uses of AVELOX tablets worldwide. Since September 1, 2000, the start of the current respiratory season, prescriptions for AVELOX tablets in the US have nearly doubled.

Bayer recently submitted to the FDA the results of an AVELOX tablets Phase IV study that included over 18,000 patients to affirm the safety and efficacy of AVELOX tablets in the treatment of ABECB[1], acute bacterial sinusitis[2], and CAP of mild to moderate severity[3].

The recommended therapeutic dose for AVELOX tablets is 400 mg taken once daily for five days for ABECB[1] and for ten days for acute bacterial sinusitis[2]

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[1] Caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Staphylococcus aureus*, or *Moraxella catarrhalis*.
[2] Caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*.
[3] Caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, or *Moraxella catarrhalis*.

and CAP of mild to moderate severity[3]. The tablet formulation of AVELOX is the only quinolone antibiotic approved for a short-course, 5-day regimen for ABECB[1].

Important Safety Information

AVELOX (moxifloxacin HCl) tablets are generally well tolerated. In clinical trials, the most common adverse events were nausea (8%), diarrhea (6%), dizziness (3%), headache (2%), abdominal pain (2%), and vomiting (2%).

Moxifloxacin tablets are contraindicated in persons with a history of hypersensitivity to moxifloxacin or any quinolone antibiotic. The safety and effectiveness of moxifloxacin tablets in pediatric patients, adolescents (less than 18 years of age), pregnant women, and lactating women have not been established. Moxifloxacin tablets have been shown to prolong the QT interval of the electrocardiogram in some patients. The drug should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia and patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents, due to the lack of clinical experience with the drug in these patient populations. Pharmacokinetic studies between moxifloxacin tablets and other drugs that prolong the QT interval such as cisapride, erythromycin, antipsychotics, and tricyclic antidepressants have not been performed. An additive effect of moxifloxacin tablets and these drugs cannot be excluded; therefore, moxifloxacin tablets should be used with caution when given concurrently with these drugs.

The effect of moxifloxacin tablets on patients with congenital prolongation of the QT interval has not been studied; however, it is expected that these individuals may be more susceptible to drug-induced QT prolongation. Because of limited clinical experience, moxifloxacin tablets should be used with caution in patients with ongoing proarrhythmic conditions, such as clinically significant bradycardia, or acute myocardial ischemia. As with all quinolones, moxifloxacin tablets should be used with caution in patients with known or suspected CNS disorders or in the presence of other risk factors that may predispose to seizures or lower the seizure threshold.

About Bayer

Bayer Corporation is a research-based company with major businesses in health care and life sciences and chemicals. The company had 1999 sales of $8.9 billion and employs approximately 22,200 people. Bayer Corporation is investing $9 billion in capital expenditures and research and development from 2000 through the year 2004. 2000 capital investment and R&D expenditures are projected to total $1.6 billion. Bayer Corporation, with headquarters in Pittsburgh, is a member of the worldwide Bayer Group, a $29 billion international life sciences, polymers and specialty chemicals group based in Leverkusen, Germany.

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