EMBARGOED Until 5:59 PM EDT/11:59 PM CEST October 17, 2005

TB ALLIANCE AND BAYER LAUNCH HISTORIC GLOBAL DRUG TRIALS FOR TUBERCULOSIS

Phase II Trials to Study Potential of Moxifloxacin to Shorten TB Treatment

Partners Commit to Affordable Pricing for Patients in the Developing World

New York, NY and Leverkusen, Germany, October 18, 2005 – The Global Alliance for TB Drug Development (TB Alliance) and Bayer Healthcare AG today announced a partnership to coordinate a global clinical trial program to study the potential of an existing antibiotic, moxifloxacin, to shorten the standard 6-month treatment of tuberculosis (TB).

If the trials are successful, the partnership aims to register moxifloxacin for a TB indication and is committed to making it affordable and accessible in developing countries where patients need it most**.** The trials will take place in Brazil, Canada, South Africa, Spain, Tanzania, Uganda, the United States and Zambia.

The Phase II clinical trial program spans four continents and will enroll close to 2,500 patients with TB. Bayer will donate moxifloxacin for each trial site and will cover the costs of regulatory filings. The TB Alliance will coordinate and help cover the costs of the trials, leveraging substantial support from the U.S. Centers for Disease Control and Prevention (CDC), the Orphan Products Development Center of the U.S. Food & Drug Administration (FDA) and the European and Developing Countries Clinical Trials Partnership (EDCTP).

"We are witnessing an historic moment in global health," said Dr. Maria C. Freire, President and CEO of the TB Alliance. "Today, we stand with Bayer, embarking on a major clinical trial program to see if this excellent antibiotic can shorten TB treatment by 2-3 months, which would significantly improve therapy. If successful, a new, shorter regimen could be available in the next five years, making the difference between life and death for millions of TB patients."

The trials will evaluate whether the substitution of moxifloxacin for one of the standard TB drugs (ethambutol or isoniazid) eliminates TB infection faster than the current standard therapy.[1] Current TB therapy is based on four drugs discovered forty or more years ago that must be administered for

six to eight months, often under the direct observation of a healthcare provider. Preclinical studies *in vivo** showed moxifloxacin reduced treatment time by two months when substituted for isoniazid, a cornerstone drug of TB treatment[2]. Moxifloxacin is approved in 104 countries to treat certain bacterial respiratory and skin infections.

"Moxifloxacin has been safely and reliably used to treat millions of patients with a variety of bacterial respiratory tract infections," said Dr. Wolfgang Plischke, head of the pharmaceuticals division of Bayer HealthCare. "Bayer is committed to working with the TB Alliance to develop a shorter TB therapy and we are proud to make a tangible contribution and to participate in the movement to achieve the Millennium Development Goal to reverse tuberculosis as a major global health pandemic by 2015."

Mycobacterium tuberculosis infects one-third of the world's population, resulting in nine million new cases of active TB and two million deaths each year. Public health experts note that a shorter TB regimen would help ease the economic burden, estimated at $16 billion a year, and enable healthcare workers to treat more patients. A shorter protocol could also reduce side effects, improve patient adherence to therapy, and save lives. When patients complete treatment successfully, there is a lower chance of relapse and the emergence of drug resistance.

"This is an important step toward developing a new generation of TB treatments. We urgently need to improve upon current TB drugs, which were developed more than 40 years ago," said Dr. Helene Gayle, Director, HIV, TB and Reproductive Health at the Bill & Melinda Gates Foundation. "By innovating with an existing product, Bayer and the TB Alliance could make an improved TB treatment available much faster than would otherwise be possible."

Two clinical trials are being conducted by the Tuberculosis Trials Consortium (TBTC) of the CDC, represented by Steering Committee Chair Dr. Neil Schluger of Columbia University. Principal investigators of the two other trials are Dr. Richard Chaisson of the Johns Hopkins University and Dr. Stephen Gillespie of the University College London, working with Prof. Andrew Nunn of the British Medical Research Council.

Current projections of TB incidence and mortality reflect the need for shorter, more effective TB therapy. An estimated 1 billion people will be newly infected between 2000 and 2020, 200 million will fall ill and 35 million will die. TB is a leading cause of death among people living with HIV/AIDS, and multi-drug resistant strains are spreading at a rate of 300,000 newly diagnosed cases a year.

About the Global Alliance for TB Drug Development

The Global Alliance for TB Drug Development (TB Alliance) is a not-for-profit, public-private partnership accelerating the discovery and/or development of affordable, new anti-TB drugs that will shorten treatment, be effective against multi-drug resistant strains, treat HIV-TB co-infection, and improve treatment of latent infection. Working with public and private research laboratories worldwide, it is leading the development of the first, most comprehensive portfolio of TB drug candidates in three decades. It operates with the support of the Bill and Melinda Gates Foundation, the Rockefeller Foundation, the United States Agency for International Development, and the Netherlands Ministry for Cooperation Development. For more information on TB drug development, moxifloxacin and the TB Alliance, please visit www.tballiance.org.

About Moxifloxacin

Oral moxifloxacin is a once-a-day therapy approved to treat: **Acute Bacterial Exacerbations of Chronic Bronchitis (ABECB)** caused by *Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Staphylococcus aureus,* or *Moraxella catarrhalis*; **Acute Bacterial Sinusitis (ABS)** caused by *Streptococcus pneumoniae, Haemophilus influenzae*, or *Moraxella catarrhalis*; **Community Acquired Pneumonia (CAP)** caused by *Streptococcus pneumoniae* (including multi-drug resistant strains*), *Haemophilus influenzae, Moraxella catarrhalis, Staphylococcus aureus, Klebsiella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydia pneumoniae;* **Uncomplicated Skin and Skin Structure Infections (uSSSI**) caused by *Staphylococcus aureus* or *Streptococcus pyogenes;* Moxifloxacin IV infusion is approved to treat **Community Acquired Pneumonia (CAP)** and **Complicated Skin and Skin Structure Infections (cSSSI)** caused by methicillin susceptible *Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae,* or *Enterobacter cloacae.*

*MDRSP, Multi-drug resistant Streptococcus pneumoniae, includes isolates previously known as PRSP (penicillin-resistant Streptococcus pneumoniae), and are strains resistant to two or more of the following antibiotic classes: penicillin (MIC ≥ 2 µg/mL), second generation cephalosporins, e.g. cefuroxime, macrolides, tetracyclines and trimethoprim/ sulfamethoxazole.

Safety Information about Moxifloxacin

Moxifloxacin is contraindicated in persons with a history of hypersensitivity to moxifloxacin or any member of the quinolone class of antimicrobial agents.

Anaphylactic reactions, some following the first dose, have been reported in patients receiving quinolone therapy including moxifloxacin.

The safety and effectiveness of moxifloxacin in pediatric patients, adolescents (less than 18 years of age), pregnant women, and lactating women have not been established.

Moxifloxacin has 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 1A (eg., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents, due to limited clinical experience. Moxifloxacin should be used with caution when given together with drugs that may prolong the QT interval (e.g., erythromycin, antipsychotics, antidepressants) and in patients with ongoing proarrhythmic conditions, such as clinically significant bradycardia or acute myocardial ischemia.

As with all quinolones, moxifloxacin 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.

In large clinical trials, the most common adverse events occurring in >3 percent of patients were nausea (7%), diarrhea (6%) and dizziness (3%). For more information, please contact Bayer clinical communications at 800.288.8370.

About Bayer HealthCare AG

Bayer HealthCare AG, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the health care and medical products industry. In 2004, the Bayer HealthCare subgroup generated sales amounting to some 8.5 billion Euro.

The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Bayer HealthCare employed 35,300 people worldwide in 2004.

Bayer HealthCare's aim is to discover and manufacture innovative products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating disease.

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* Preclinical activity in animals does not necessarily imply clinical effectiveness in humans.

[1] Nuermberger, EL et al. Moxifloxacin-containing regimen greatly reduces time to culture conversion in murine tuberculosis. *American Journal of Respiratory and Critical Care Medicine* 2004; 169: 421-426.

[2] Nuermberger, EL et al. Moxifloxacin-containing regimens of reduced duration produce a stable cure in murine tuberculosis. *American Journal of Respiratory and Critical Care Medicine* 2004;170:1131-1134