



**FOR IMMEDIATE RELEASE**

**TB ALLIANCE AND BAYER WIN AWARD FOR INNOVATIVE LICENSING OF DRUG BEING TESTED FOR THE TREATMENT OF TUBERCULOSIS**

**Licensing Executive Society Awards the “Deal of Distinction” Prize for Top Licensing Agreement in the Industry-University-Government Category**

**NEW YORK CITY (September 13, 2006)** -- The Global Alliance for TB Drug Development (TB Alliance) and Bayer HealthCare AG today were awarded top honors from the Licensing Executive Society (USA and Canada) for an innovative agreement allowing the start of global clinical trials of a drug that may prove effective in treating tuberculosis (TB).

The prestigious 2005 Deal of Distinction Award recognizes worthy transactions involving the transfer and licensing of intellectual property using creative and innovative solutions to business issues. This year, the award was given to only six deals.

“The partnership between the TB Alliance and Bayer Healthcare required a fresh look at how to leverage the strengths of private and public organizations to solve a global health crisis of growing proportion,” said Gerald J. Siuta, PhD, of the TB Alliance. “We are proud of this agreement and honored to receive the recognition from LES.”

Last October, the TB Alliance and Bayer announced a partnership to coordinate a global clinical trial program to study the potential of Bayer’s existing fluoroquinolone antibiotic, moxifloxacin, to shorten the standard 6-month treatment duration for TB.

The agreement was extremely important in the global health community because *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 treatment regimen would help ease the estimated at \$16 billion annual economic burden, and enable healthcare workers to treat more patients. A shorter protocol may 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 resistant forms of TB which pose a growing threat to developed nations.

"I am proud that LES chose to recognize the Bayer/TB Alliance collaboration with this award. If the clinical trial program with our drug is successful this agreement will deliver a significant step forward in the search for new therapies to treat tuberculosis, one of the World's major infectious diseases," said Kevin Kuehm, VP of Business Development and Licensing North America for Bayer.

The deal won the award because (1) it was the first in which a company allowed a currently marketed drug to be studied for a disease that is most prevalent in the developing world; (2) the partnership engaged a Big Pharma company with a not-for-profit, public-private partnership in the testing of a drug for a new use; and (3) if successful, the collaboration envisions registering moxifloxacin for a TB indication. As part of the agreement, Bayer committed to making moxifloxacin affordable and accessible in developing countries where patients need it most. The drug is currently approved in 104 countries for the treatment of a variety of bacterial respiratory tract infections.

The TB Alliance is a not-for-profit, public-private partnership that is working to discover or develop 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.

Phase II moxifloxacin trials are now taking place in Brazil, Canada, South Africa, Spain, Tanzania, Uganda, the United States and Zambia and will enroll close to 2,500 patients with TB. Phase III trials are expected to get underway in early 2007.

Bayer will donate moxifloxacin for each trial site and will support the regulatory filings. The TB Alliance will coordinate and help cover the costs of the trials. If successful, a new, shorter treatment regimen could be available in the next five years, significantly improving the treatment options 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 existing TB treatment regimens. 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* have shown that moxifloxacin reduces treatment time by two months when substituted for isoniazid, a cornerstone drug of TB treatment.

### **About the Global Alliance for TB Drug Development**

The Global Alliance for TB Drug Development (TB Alliance) is a not-for-profit, product development 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 & Melinda Gates Foundation, the Rockefeller Foundation, the UK Department for International Development (DFID), the United States Agency for International Development (USAID), the Netherlands Ministry of Foreign Affairs (DGIS) and Irish Aid. For more information on TB drug development and the TB Alliance, please visit [www.tballiance.org](http://www.tballiance.org).

### **About Bayer HealthCare**

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen,

Germany. Bayer HealthCare generated sales amounting to some 9.4 billion euros and employed 33.800 people worldwide in 2005. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals divisions. The new Pharmaceuticals division was established on January 1, 2006, and comprises the former Biological Products and Pharmaceutical divisions. Pharmaceuticals now has three business units: Hematology/Cardiology, Oncology and Primary Care. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

**CONTACT:**

Brad Tytel  
Global Alliance for TB Drug Development  
Tel: +1 212 227 7540 x202  
[bradley.tytel@tballiance.org](mailto:bradley.tytel@tballiance.org)

Staci Gouveia  
Bayer Healthcare  
Tel: +1 203 812 6152  
[staci.gouveia.b@bayer.com](mailto:staci.gouveia.b@bayer.com)