

***THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT CALLS FOR
MOBILIZATION AGAINST THE TB EPIDEMIC***

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Brussels, Belgium— On the eve of World TB Day, the Global Alliance for TB Drug Development stresses the urgent need for new drugs against tuberculosis (TB). This appeal is based on scientific data pointing to the growing incidence of TB worldwide, the expected sharp increase in the number of HIV-TB coinfecting individuals, the growth of multidrug-resistant TB (MDR-TB) and the challenges in expanding the standard DOTS (Directly Observed Treatment – Short Course) strategy. Stressing the urgent need for new TB drugs and highlighting that related R&D is still largely insufficient, the Global Alliance argues that there is a large potential market for new drugs.

The annual incidence of TB rose from 8 million in 1997 to 8.4 million in 2000 and it is expected to rise further to 10.2 million new cases a year by 2005. The TB incidence increased most dramatically in African countries hit by the Aids epidemic. The Global Alliance highlights that the number of individuals coinfecting with TB and HIV, which is already over 10 million, is expected to dramatically increase in the next 10 years. HIV-TB coinfecting individuals are 30 to 50 times more at risk of developing active TB. Further compounding the problem, multidrug resistant TB is emerging. MDR-TB cases have been detected in over 100 countries. Some have estimated that more than 400,000 new cases of MDR-TB will develop every year.

No new class of TB drug has been developed in more than 30 years. Until recently, progress in Tuberculosis drug development has been impeded by two major factors: (1) the belief that there was little need for new agents and (2) the high cost of development coupled with the perception that the potential global market was insufficient to guarantee return on investment.

Preliminary findings from Global Alliance research demonstrate that an anti-TB drug that reduces the period of treatment from 6 months to 2 months could capture between \$300 million and close to \$400 million (US\$) of the total annual worldwide market for TB drugs. This could be a conservative estimate. A drug that not only reduces treatment to 2 months but also is effective against MDR-TB and dramatically shortens the treatment for LTBI (latent TB infection), particularly in patients who are HIV-positive, would capture a substantially larger market.

The source of these potential market data, *The Pharmacoeconomics of TB Drug Development*, is a study of the Global Alliance that aims to provide the data required for industry, governments, global financial and health organizations and philanthropic institutions to enable informed decisions about investing in TB drug development. This report is scheduled to be published in May 2001.

New vision, new partners, new TB drugs for all

“We believe that this research into the pharmacoeconomics of anti-TB drugs will reinvigorate the interest of the pharmaceutical industry and public research organizations in the battle against a disease that is not only a tremendous burden to the poorest countries but also a threat to all nations,” said Giorgio Roscigno, acting CEO of the Global Alliance for TB Drug Development.

The Global Alliance also identified gaps in the R&D chain that constitute significant barriers to new drug development. In its *Scientific Blueprint for TB Drug Development*, which will be published as a supplement to the journal *Tuberculosis* in April 2001, the Global Alliance identifies R&D gaps at each stage of the process—from basic research and discovery to preclinical and clinical trials, up to regulatory approval — and suggests solutions and roadmaps for scientists.

Background information

Approximately 1.86 billion people - about one-third of the world’s population - are infected with the tuberculosis bacterium. Every year an estimated 8.4 million people develop active TB, and 1.9 million die from the disease.

TB can be cured. DOTS, the internationally recommended WHO strategy to control TB is very effective. However, its progress has been unsatisfactorily slow: only 23% of patients are now covered by DOTS. Among the factors making the DOTS expansion difficult and costly is the required treatment duration of 6 to 9 months. To be expanded faster, DOTS needs to be simplified and a drug capable of further reducing significantly the treatment period would produce a dramatic improvement in treatment access.

Due to poor compliance with treatment outside of successfully administered DOTS programmes as well as many instances of misdiagnosis, misprescribed treatment, and poor drug supply, multidrug-resistant (MDR) strains of TB have developed and spread, further compounding the problem. Some have estimated that more than 400,000 new cases of MDR-TB will develop every year. Treatments for multidrug-resistant strains last between 18 and 24 months and are significantly more expensive, less effective, and more toxic than treating drug-susceptible TB.

A new anti-TB drug that meets the Global Alliance’s goals of reduced treatment duration to 2 months, effectiveness against MDR-TB, and improved treatment of latent TB infection (LTBI), would address the needs of millions, accelerate global control and elimination of the disease, and dramatically reduce the overall costs of treating the disease. Reducing the overall cost of TB treatment is an especially important need in poorer countries with a high incidence of TB.

The Global Alliance for TB Drug Development

The *Global Alliance for TB Drug Development* operates as a not-for-profit, public-private partnership organization with offices in Brussels, Cape Town, and New York. Launched in October 2000 with the goal of providing new medicines and equitable access to improved treatments for TB, the Global Alliance will function as a lean, virtual R&D organization that outsources R&D projects to its partners or to industry.

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Its R&D strategy will concentrate on building a portfolio of promising drug candidates and managing that portfolio by initiating cooperative deals with public and private partners. For specific investments, the Global Alliance will also consider providing staged funding and expert scientific and management guidance. These efforts will achieve the Global Alliance's mission: to accelerate the discovery and/or development of cost-effective new TB drugs that will shorten treatment, be effective against MDR-TB, and improve treatment of LTBI. The Alliance is associated to the Stop TB Initiative, a global movement to accelerate social and political action to stop the unnecessary spread of tuberculosis around the world.

Stakeholders of the Global Alliance for Tuberculosis Drug Development

- American Society for Tuberculosis Education and Research
- American Thoracic Society
- Association of the British Pharmaceutical Industry
- Bill & Melinda Gates Foundation
- European Commission
- Global Forum for Health Research
- International Union Against Tuberculosis and Lung Disease
- Lupin Laboratories
- Médecins Sans Frontières/Doctors Without Borders
- Medical Research Council of South Africa
- Novartis India Ltd
- Research Triangle Institute
- Rockefeller Foundation
- Royal Netherlands Tuberculosis Association
- Sequeella Global Tuberculosis Foundation
- Stop TB Initiative
- TDR (Tropical Diseases Research)/ UNDP – World Bank – WHO
- U.K. International Development Secretary
- U.S. Agency for International Development
- U.S. Centers for Disease Control
- U.S. National Institutes of Health
- U.S. National Tuberculosis Center
- Wellcome Trust
- World Bank
- World Health Organization

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