



THE GLOBAL ALLIANCE FOR TB Drug Development

New vision, new partners, new TB drugs for all

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DEVELOPMENT OF NEW ANTI-TB TREATMENTS AFFORDABLE IN WORST-HIT COUNTRIES IS AIM OF NEW, GLOBAL PUBLIC-PRIVATE PARTNERSHIP

*Global Alliance for TB Drug Development commits to delivering its
first new drug by 2010*

*Total funding expected to exceed US\$150 million; Gates and
Rockefeller foundations announce commitments totaling US\$40
million; Pharmaceutical R&D chiefs offer support*

BANGKOK, October 10, 2000 – The Global Alliance for TB Drug Development, a public-private partnership for the discovery of new drugs to treat one of the world's deadliest infectious diseases, was inaugurated today at the International Conference on Health Research for Development by its stakeholders from governments, non-governmental organizations, industry and foundations. The Global Alliance also unveiled a Scientific Blueprint for the discovery and development of new anti-tuberculosis (TB) drugs.

Total funding for the Global Alliance from governments, non-governmental organizations, industry, foundations and multi- and bi-lateral organizations is expected to exceed US\$150 million over the next 5 years. The Bill and Melinda Gates Foundation has announced a grant of US\$25 million and the Rockefeller Foundation is expected to commit US\$15 million.

The pharmaceutical industry has indicated its strong support and willingness to engage in partnerships with the Global Alliance. The industry's position was indicated in a statement by the "Hever" group of senior R&D directors from the world's largest pharmaceutical companies.

Commitment and new resources to produce first new class of TB drug in 30 years

The Global Alliance is committed to improving TB control by discovering, developing and making anti-TB drugs available, particularly in the countries worst hit by the disease,

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at prices that are affordable to their populations. The Global Alliance expects the first new drug to be registered by 2010, which will be one of several new drugs the Alliance intends to generate. These cost-effective new TB drugs will shorten the duration of TB treatment or simplify its completion; improve the treatment of latent TB infection; and be effective against multi-drug resistant TB (MDR-TB).

There has been no new class of TB drugs developed in more than 30 years and the existing medicines and treatment regimes used to administer them are losing the battle against the disease. Drugs for treating the infection and controlling the symptoms of TB are losing their efficacy as the bacillus continues to build up resistance to them. And though the most effective course of treatment known as Directly Observed Treatment Short Course (DOTS) has a high cure rate, it is hampered by a 6 to 9 month course that hinders effective implementation.

Dr. Gro Harlem Brundtland, Director-General of the World Health Organization (WHO), a partner of the Global Alliance, said, "Tuberculosis is not only a cause of misery and death – it is a major impediment to social and economic development. The world's poorest nations need new drugs that will reduce both the total length of treatment and the frequency of drug administration."

Treatment, cure is key to preventing further spread of disease

TB causes more than 2 million deaths each year, or about 5,500 deaths every day, most often in the world's poorest countries. The disease is rapidly spreading among HIV-infected populations and one-third of HIV patient deaths are the result of TB. One-third of the world's population is currently infected with TB and each year 8 million people develop the disease in its active form.

The Alliance's acting chief executive officer and former medical director for anti-infectives at Aventis Pharma, Dr. Giorgio Roscigno said, "Since each TB patient can infect hundreds of others, the best way to prevent TB is to treat and cure people who have it and spread it. The creation of the Global Alliance, the most important development in TB control since the WHO declared the disease a global emergency in 1993, brings us much closer to a new treatment."

TB is a disease of the poor. Its greatest burden falls on those who can least afford to pay for prevention or treatment. The average cost for a pharmaceutical company of discovering and getting a new drug to the market is estimated to be at least US\$300 million. With little prospect of an adequate commercial return in those parts of the world where TB is most prevalent, the traditional method of relying on market mechanisms to obtain new drugs is not working. The challenge requires novel, creative approaches.

New vision, new partners, new TB drugs for all

The Global Alliance for TB Drug Development offers a new approach to the discovery and development of new medicines for TB. It is a genuinely global partnership which brings together the pharmaceutical industry's knowledge and expertise in drug discovery and development with the public sector's depth of expertise in basic biology and field studies.

The Global Alliance says it is already in discussions with a number of pharmaceutical companies regarding funding and 'in-kind' donations of promising candidate compounds.

Expert scientific team to emphasize joint ventures with TB-endemic countries

The Global Alliance will work to raise additional funds, and then finance a selected number of promising drug R&D projects. A globally acknowledged committee of experts, known as the Scientific Advisory Committee, will select projects for funding from among proposals submitted through a competitive application (request for proposals) process. In addition the Global Alliance will aggressively pursue and initiate deals with targeted public and private institutions. The selected projects will be built around public-private partnerships. Particular emphasis will be placed on initiating activities involving institutions in TB endemic countries.

“New drugs, which are affordable to communities in areas of high TB transmission, are urgently needed if the impact of TB is to be contained,” said Dr. Malegapuru William Makgoba, a Global Alliance board member and president of the Medical Research Council of South Africa.

A blueprint for drug discovery

The Global Alliance’s Scientific Blueprint for TB Drug Development, released today, is intended as a guide for scientists and investigators in academia, industry and the public sector in all aspects of TB drug discovery and development.

“This is the most exhilarating moment for TB drug development in over two decades,” said Dr. Rick O'Brien, chief of research in the Division of TB Elimination at the Centers for Disease Control and Prevention in Atlanta, Georgia, and chair of the Global Alliance’s scientific advisory committee. “At long last technical advances and heightened political commitment to address the global TB problem are converging.”

The Global Alliance’s R&D strategy will concentrate on building a portfolio of promising drug candidates, and ‘virtually’ 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.

Funds, donations to drive aggressive, ‘virtual’ R&D company

Funds, like those announced today, are expected to come mainly from governmental funding agencies, foundations and philanthropic donations. Pharmaceutical industry contributions will be mainly in the form of freely donated drug R&D expertise and related technology. Initial funding will enable the Global Alliance to establish its management team and to set an initial group of projects. If the Global Alliance’s funding targets are achieved, it is expected that the first product to be generated by the Global Alliance will be registered by 2010.

The Global Alliance for TB Drug Development is a public-private partnership operating as a not-for-profit organization with offices in Brussels, Cape Town and New York. Operationally independent from its donors, the Alliance is modeled after a small, virtual R&D company and will be an aggressively managed and lean entity. A chief executive officer will lead the company, reporting to a board of directors chaired by Dr. Carlos Morel, director of the WHO Special Program for Research and Training in Tropical Diseases, and consisting of members from Chiron, a leading biotechnology firm; Warburg Pincus & Co., an investment bank; the National Institute of Allergy and Infectious Diseases (U.S.); the Medical Research Council of South Africa; the Rockefeller Foundation; and the National Institute of Public and Environmental Health (Netherlands).