

OVERCOMING BARRIERS TO ACCESS

Research and Development

The APG remains committed to maximising global healthcare capacity through the development of new medicines, as well as more easily administered new formulations of existing drugs. Members of the APG believe that enhancing the access to essential drugs is their primary role.

Pfizer's collaboration with the Special Programme for Research and Training in Tropical Diseases of the World Health Organisation (WHO/TDR), announced in October 2006, is part of a new effort to link the research resources of a major pharmaceutical company to a global network of discovery research. It will speed up the search for new drugs to combat some of the world's most deadly parasitic diseases, including malaria, leishmaniasis, African trypanosomiasis, onchocerciasis, schistosomiasis and Chagas disease.

As part of this collaboration, Pfizer has opened up its library of medicinal compounds and has brought scientists from developing countries into Pfizer's laboratories for training in drug discovery techniques and state-of-the-art tools. Under the arrangement, scientists in institutes affiliated with the WHO/TDR-sponsored Compound Evaluation Network are testing thousands of compounds from the Pfizer library. In a process called screening, the researchers are seeking to identify hits - compounds that show initial activity against a range of tropical parasites. Following training, they will return to their home countries to deploy their new knowledge and skills.

Pfizer believes public-private research collaborations are vital for tackling health challenges in developing countries. The company is already exploring ways in which the collaboration with WHO/TDR might be expanded to further aid in the search for drugs with the potential to treat tropical diseases. Pfizer hopes the new collaboration will encourage other companies to join and expand the WHO/TDR Networks, and to explore further collaborations with developing country researchers in discovery research.

In less than four years **Bristol-Myers Squibb** has delivered eight new medicines. With a focus on areas of significant medical need, Bristol-Myers Squibb is working to discover and develop treatments specifically for diseases that affect the developing world for example hepatitis and HIV/AIDS.



Abbott's work on improving its HIV treatments continues with the new tablet form of Kaletra®, lopinavir/ritonavir, called Aluvia® in some countries, which is equally effective when taken with or without food, does not need to be refrigerated and provides the same daily dosage in fewer pills than the original Kaletra capsules. This latest innovation, in addition to offering added convenience and tolerability, is a major step to improving access to Kaletra in areas where refrigeration is not available. Most recently, Abbott received U.S. Food and Drug Administration and European

Photo: ARV therapy is already restoring hope for families across Africa

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Medicines Agency approval for a new lower-strength formulation of Kaletra, the first protease inhibitor of its kind for paediatric use.

The **Lilly Multi-Drug Resistant Tuberculosis Partnership** is tackling the disease with existing medicines, but the regimen is long and requires isolation from family and friends. This is why it is not surprising that many people fail to complete treatment, giving rise to drug-resistant TB strains. Lilly recognises that to encourage compliance, newer, fast-acting medicines are needed. To fill the pipeline, Lilly and its partners are supporting a new, non-profit research facility in Seattle, USA, that will draw upon global resources for pioneering research. This new charity will scour millions of molecules in medicinal libraries donated by Lilly and another manufacturer to identify promising molecules. The organisation will focus exclusively on early-phase drug discovery.

Tibotec Pharmaceuticals (a subsidiary of **Johnson & Johnson**) has long been a pivotal player in the R&D of medicines to address the HIV/AIDS epidemic. In 2004, Tibotec completed an agreement with the International Partnership for Microbicides (IPM) to provide a royalty-free licence and technology transfer for the development, manufacture, and distribution of dapivirine gel (TMC120) as a topical vaginal microbicide. The collaboration marked the first partnership in the microbicide field between a major health care company and a public-private partnership, such as IPM. IPM was established in 2002 to accelerate the development of and access to microbicides for women in developing countries.

- *“This agreement is a major milestone in global efforts to develop a microbicide for all women around the world, and is a model of the innovative collaboration that is crucial to reversing the AIDS epidemic,”* said Dr Peter Piot, executive director of UNAIDS in Geneva. *“Microbicides must be at the centre of a comprehensive prevention agenda for women and girls, who account for about half of all HIV infections worldwide.”*

In 1988, **Merck & Co., Inc.** researchers were the first to demonstrate that the inhibition of the protease enzyme would prevent replication of HIV. The following year, Merck & Co., Inc. scientists published the first crystal structure for HIV protease. These insights led to the development of a new, powerful class of medicines to treat HIV and AIDS, namely protease inhibitors. In 1999 Merck & Co., Inc. scientists discovered efavirenz, a non-nucleoside reverse transcriptase inhibitor, and in 2008 introduced the first in a new class of anti-HIV medicines called

integrase inhibitors. Their researchers continue to work on HIV antiretroviral drugs that will work via new mechanisms of action to treat HIV.

Collaboration between **Wyeth** and the WHO continues to evolve on the clinical development of moxidectin, a new macrofilacidal agent with the potential to make global disease eradication an attainable goal, especially in sub-Saharan Africa where the disease is predominant. Incoming data from the Phase 2 clinical study, which began in Ghana in 2006, continues to be very positive. Consequently, preparations for the pivotal Phase 3 study are under way in the two sites that have been identified to date, Liberia and the Democratic Republic of Congo.

Wyeth’s commitment to the WHO to provide funding support for Phase 3 studies was first announced by the company at the 11th Joint Action Forum (JAF) meeting in Tanzania (2006). Since then, the two parties have been working closely to finalise a comprehensive legal agreement and terms of reference so that the long-anticipated Phase 3 studies can be successfully launched in the third quarter of 2007.

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