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2006 Commitments - Health

The Polypill for Prevention of Cardiovascular Disease

Focus Area: Health

Commitment By: World Heart Federation; CNIC (Spanish National Centre for Cardiovascular Research)

First Year Cost: \$2,250,000

Total Estimated Value: \$9,000,000

Commitment Duration: 10 years

Objective:

To save the lives of people severely affected by cardiovascular disease by developing, by 2009, a polypill-a fixed-dose combination of ace inhibitor, statin and aspirin therapies for secondary prevention of cardiovascular disease in postmyocardial infarction (heart attack) patients. Working in partnership, CNIC and the World Heart Federation commit to develop, produce and deliver the polypill, for the prevention of cardiovascular disease in heart attack patients.

Commitment Announcement:

The World Heart Federation's primary contribution will be in the area of advocacy and education. CNIC, a creative public-private partnership between the Spanish Ministry of Health and private investors, will be responsible for the bio-equivalent studies (clinical trials) in patients, for managing relations with the initial subcontracted manufacturer, and for producing an effective polypill that is ready for distribution in pilot countries in 2010.

Background:

The phrase "Access to Medicines" has been applied almost exclusively in the context of infectious diseases and it is time for that to change. Chronic diseases, including cardiovascular disease and diabetes, now account for 60% of global mortality, with 80% of that burden in low- and middle-income countries. 17.5 million people die each year of cardiovascular disease, many prematurely.

The new concept of the polypill to prevent cardiovascular disease was evaluated three years ago through an extensive literature survey of various large meta-analyses of four cardiovascular risk factors: cholesterol, arterial blood pressure, platelet aggregation, homocysteine. This research was published in a landmark article in the British Medical Journal in June 2003, which concluded that a fixed combination drug (a polypill) could reduce coronary heart disease events by 88% and strokes by 80% in individuals who are at risk.

Many of the stand-alone medications that have successfully cut premature mortality from heart disease in Western populations are now off-patent. However, for patients and health-care providers in the developing world it remains expensive and logistically complicated to combine different medications for maximum effectiveness, even when generic drugs are available. The polypill is estimated to be one-fifth the cost of currently available therapies. It is also expected that the polypill will substantially increase patient compliance with their prevention-medication regimens. The polypill could save the lives of post-myocardial infarction patients and high-risk individuals in low- and middle-income countries, as well as low-income patients in richer countries who would otherwise have limited treatment options.

The potential impact in the proposed pilot countries could be tremendous: In 2005, cardiovascular deaths accounted for 32% of all deaths in Spain and in China, and for 29% of deaths in India.

Although the degree of potential private-sector resistance, trade-agreement stumbling blocks, and drug-distribution insufficiencies is not yet known, cardiovascular-disease patients will benefit tremendously from an affordable polypill. Those who stand to gain the most are the underserved patients in low- and middle-income countries, whose access to care is usually dependent upon their ability to pay. This is one of the reasons that the polypill has been recommended in recent reports by the World Health Organization.

Point of Contact:

Janet Voute, Chief Executive Officer, World Heart Federation
Helen Anderson, Chief Operating Officer, World Heart Federation

Geographic Scope:

Spain ; China

Anticipated Launch:

9/19/2006

Milestones and Key Actions:

March 2007:

- § Selected pharmaceutical partner end of 2006.
- § Analysis of patents (freedom to operate) (in course).
- § Drug components and dosage selection (finished December 2006): Selection of a combination (priority) and 5 alternative combinations to keep as backup in case of either galenic or patent difficulties.
- § Consultation to Regulatory Authorities in a European country, to the EMEA and in USA (FDA) (end 2007).
- § Bioequivalence and tolerability in normal volunteers (early 2008).
- § Clinical studies on patients adherence to pharmacological treatment (early 2008).
- § Presentation of polypill dossier to regulatory authorities (end 2009).
- § Clinical studies comparing treatment adherence with polypill and conventional treatment (2009 - early 2010).
- § Manufacturing and polypill distribution (early 2010).

June 2007:

Patent Analysis:

- Performed analysis of patents, a task that is routinely performed in order to know the scientific activity around new patents published in cardiovascular prevention.
- The current formulation strategy is able to be developed without infringement of published patents.

Pharmaceutical development:

- Sought out scientific advice with Regulatory Agencies.
- After selection of different active drug combinations and dosages, experimental analytical and pharmaceutical work has started with the aim of selecting the best polypill prototypes to be scaled-up.
- Compatibility data of main formulation and alternatives that have been found are encouraging.

Pre-clinical biological studies:

- Design of bioavailability studies in animals to determine the pharmacokinetics of the different polypill formulations in animals compared to current single marketed reference products.

Clinical development:

- Design of bioequivalence clinical studies in volunteers to determine the comparative pharmacokinetics of polypill candidate versus reference comparators.
- Design of a set of clinical trials in high risk, cardiovascular disease patients, in order to demonstrate the beneficial effect of the polypill, in terms of treatment adherence and better control of risk factors.
- Seeking funding for performing future clinical trials.

Findings:

- The polypill is estimated to be one-fifth the cost of currently available therapies for prevention of cardiovascular diseases.
- It is expected that the polypill will substantially increase patient compliance with their prevention-medication regimens.

The polypill could save the lives of post-myocardial infarction patients and high-risk individuals in low- and middle-income countries, as well as low-income patients in richer countries who would otherwise have limited treatment options.

Partnership Opportunities:

Additional partners are sought who can contribute manufacturing and distribution capability in pilot countries, can advocate for the polypill at both national and global levels, and can share experience gained in the access-to-medicine debates over HIV/Aids anti-retroviral therapies.