Role of the Private Sector in Combating Malaria

Manos Perros
Pfizer Global Research & Development

Musée de la Croix-Rouge, Geneva
November 12, 2009
Drug Development and the Evolving R&D Ecosystem

Research hospitals

CROs

Regulators

Biotech

Manufacturing

Joint ventures / PPPs

HTA

Universities

Doctors

Physicians

Pharmacists

Joint ventures / PPPs

Universities

Basic science

Applied research

Funding

Pre-competitive research

Open innovation

People

Ideas

Patient focus

Innovative product

Innovative idea

Technology platform

Medicines for Malaria Venture

Pfizer

$800 - $1,300 m

10 - 12 years
Inescapable Truths of Medicines Discovery

**Discovery (2–8 Years)**
- Preclinical Testing Laboratory and Animal Testing
- Phase I 20–80 Healthy Volunteers
- Phase II 100–300 Patient Volunteers
- Phase III Up to 5,000 Patient Volunteers
- Regulatory Review & Approval
- Additional Post-Marketing Testing

**Compound Success Rates by Stage**
- 5,000–10,000 Screened
- 250 Enter Preclinical Testing
- 5 Enter Clinical Testing
- Approved by Regulators

**COST**
- 10-20 years from idea to bedside
- Long-term safety responsibilities and legal liabilities

*Need best in class R&D to progress your idea to a drug*
Malaria Overview

- Over 85% of Deaths Occur in Sub-Saharan Africa
- Pregnant women and young children are at highest risk of death
- Renewed focus on R&D with money from Gates and MMV and others
- Current and near term therapies dominated by artemisinin derivative combinations
- Development of resistance is a real risk

WHO Malaria Strategy – 4 Key Interventions

ACTs
Indoor Spraying
Malaria
IPTp
ITNs

Source: WHO Malaria Report 2008

ACT: Artemisinin-based Combination Therapy
IPTp: Intermittent Preventive Treatment in pregnant women
ITNs: Insecticide-treated bed nets
Industry DDW R&D is Increasing and Increasingly Collaborative

© IFPMA 2009: From IFPMA to WHO EWG 12 Jan 09.
What Can Private Industry Offer?

- **IP and contract negotiation experience**
- **Clinical trial partnerships**
- **Safety & risk management**
- **Global manufacturing network**
- **Distribution & sales**
- **Supply chain integrity**

- **Medicinal chemistry and biotherapeutics**
- **Animal health/parasitology**
- **Target identification**
- **Compound libraries**
- **Scientific expertise**
- **State-of-the-art research laboratories**

- **APPLIED PRODUCT DEVELOPMENT**
- **APPLIED RESEARCH**
- **FUNDING**
- **BASIC SCIENCE**
- **OPEN INNOVATION**
- **PRE-COMPETITIVE RESEARCH**
- **IDEAS**
- **PEOPLE**
- **INNOVATIVE PRODUCT**
- **Pfizer**

**Medicines for Malaria Venture**

$800 - $1,300 m

10 - 12 years
Industry is Committing Resources Through Multiple Mechanisms

**Independent Efforts**
- Abbott
- Amgen
- AstraZeneca
- Bayer
- Eisai
- Genzyme
- Johnson & Johnson
- Lilly
- Merck
- Pfizer
- Sanofi-Aventis
- Sigma-Tau
- Schering-Plough
- Wyeth

**Partnerships**
- Aeras
- DNDi
- Gavi
- International AIDS Vaccine Initiative
- International Vaccine Institute
- Malaria Medicines for Malaria Venture
- PATH
- TB Alliance

**Industry Dedicated DDW R&D Centers**
- Lilly
- Novartis
- AstraZeneca

(Current industry involvement & partnerships - illustrative only - not comprehensive)

© IFPMA 2009: From IFPMA to WHO EWG 12 Jan 09
Early Engagement to Expand and Optimise Screening

• Pfizer compound library made available to screen for compounds having anti-malarial potential
• Screening to be carried out at Griffith University, Australia
• Pfizer and MMV to determine which compounds are suitable for progression into potential drugs
• Follows existing collaboration with WHO TDR:
  • Screen for inhibitors of 6 disease-causing organisms, including *P. falciparum*
  • 10,000 compounds screened – including vet med and some previous CANs

*in vitro* *P. falciparum* screen

Analyze data and identify leads

Thousands of compounds

Medicines for Malaria Venture
Azithromycin/Chloroquine (AZCQ) Fixed Dose Combination

- Excellent efficacy seen in two multi-country trials in sub-Saharan Africa (≥ 98% efficacy)
- Activity against falciparum malaria and sexually transmitted infections should help improve pregnancy outcomes
- Plans to conduct a large multi-country IPTp trial in countries where the current standard of care is failing

Collaboration between Pfizer, MMV, and London School of Hygiene and Tropical Medicine (LSHTM)
**Eurartesim® (DHA/PQP)**

- Developed jointly by MMV and Sigma-Tau
- Novel fixed-dose ACT for uncomplicated *P. falciparum* malaria
- Pfizer license and supply agreement with Sigma-Tau

**Existing Therapies**

- Camoquin Plus®
- Metakelfin®
- Dualkin®

Manufactured and distributed from Pfizer’s facilities in Dakar, Senegal
MMV Vital to Our Near- and Long-term Projects for Patients

- **Existing Key Therapies for Treatment and Prevention**
- **New Artemisinin Combination Therapy**
- **Intermittent Preventive Treatment for Pregnant Women**
- **Portfolio Life Cycle Developments: Discovery of New Medicines**

<table>
<thead>
<tr>
<th>Today</th>
<th>2010/2011</th>
<th>Medium-Term Future</th>
<th>Long-Term Future</th>
</tr>
</thead>
</table>

**Developments:**
- **Today**
- **2010/2011**
- **Medium-Term Future**
- **Long-Term Future**