Introducing ‘Medicines for Malaria Venture’

UNICEF Manufacturers Meeting
1st Novembre 2006

Renia Coghlan
MMV In a Nutshell

- See [www.mmv.org](http://www.mmv.org) for background and much more
- Established in 1999, started business in 2000
- Discover, Develop, Deliver....Medicines...for Malaria
- Geneva Based: Swiss foundation (not for profit)
- Public Private Partnership (PPP or PDP)
- 19 Products in the Pipeline, 5 late stage products
- Funding from Foundations, Gvts, Companies
- 19 Staff; 10 Science, 2 Access and Delivery
- Core Objective: Contribute to Public Health Impact
Discovery

Exploratory Development

Full Development

Registration

Large Amounts of Candidate Medicine Synthesized

Clinical Data Analysis

Candidate Medicine Tested in 3-10,000 Patients (Phase III)

Studies in Healthy Volunteers Phase I

Project Team and Plans

Synthesis of Compounds

Screening

Early Focus …
May 2006 – 2010, $263m - but conditional on milestones – including A&D milestones

MMV - Medicines for Malaria Venture
funding from Foundation to 2010 (May 2006)

(Total Received/Pledged $263 Million)
### MMV Portfolio 3rd Q 2006

<table>
<thead>
<tr>
<th>Exploratory</th>
<th>Discovery</th>
<th>Preclinical</th>
<th>Development</th>
<th>Regulatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSAC antagonists</td>
<td>Novel Liver Stage Antimalarials</td>
<td>OZ Next Generation</td>
<td>Enantioselective 8-aminoquinoline</td>
<td>OZ + PQP RBx11160 + Piperaquine Tablet, Pediatric and Intravenous</td>
</tr>
<tr>
<td>Pf enoyl-ACP reductase (Fab I)</td>
<td>Pf protein farnesyl-transferase (Pf-PFT)</td>
<td>New dicationic molecules</td>
<td>Isoquine (an improved aminoquinoline)</td>
<td>AQ-13 New aminoquinoline</td>
</tr>
<tr>
<td>Cameroonian Medicinal Plants</td>
<td>4(1H)-pyridones Back ups</td>
<td>4(1H)-pyridone GW308678</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Projects as Part of the Novartis Institute for Tropical Diseases Collaboration</td>
<td>Falcipain (cysteine protease)</td>
<td></td>
<td></td>
<td>Pyronaridine - Artesunate</td>
</tr>
<tr>
<td>Novel Macrolides</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dihydrofolate reductase (DHFR)</td>
<td></td>
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</tbody>
</table>

#### Initially Profile For Uncomplicated Malaria and with support of Pediatric Formulations
- Efficacy against drug resistant strains
- Cure within three days
- Low propensity to generate rapid resistance
- Safe in small children (< 6 mos.)
- Safe in pregnancy
- Appropriate formulations and packaging
- Low cost of goods
**Criteria for Development**

- **For Uncomplicated Malaria**
  - Efficacy against drug resistant strains
  - Cure within three days
  - Low propensity to generate rapid resistance
  - Safe in small children (< 6 mos.)
  - Safe in pregnancy
  - Appropriate formulations and packaging
  - **Low cost of goods**

- **Further indications of interest:**
  - Severe malaria
  - Intermittent treatment in pregnancy
  - (Intermittent treatment in early infancy)
  - Treatments suitable for emergency situations e.g. single dose
  - *P. vivax* malaria (including radical cure)
  - Transmission blocking
  - Chemoprophylaxis
## Results of Calls for Letters of Interest

<table>
<thead>
<tr>
<th>ESAC Review</th>
<th>Proposals</th>
<th>Short-listed</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 1999</td>
<td>100</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>January 2001</td>
<td>84</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>November 2002</td>
<td>106</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>March 2005</td>
<td>81</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>April 2006</td>
<td>107</td>
<td>16</td>
<td>7</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>478</strong></td>
<td><strong>62</strong></td>
<td><strong>35</strong></td>
</tr>
</tbody>
</table>
• Reduces Risk
• Creates Internal Synergies
• Optimize use of Resources
• Targets Resources to Mission
  - in MMV’s to Health Impact/equity
• Becomes an iterative ‘virtuous circle’
R&D: A contractual balance of obligations and benefits

**MMV Input**
- $$
- Drug Profile
- Background IPR
- Link to WHO/Policy
- Malaria Expertise

**Public**

**MMV Gets**
- Drug ‘Rights’ in Endemic Countries
- IPR in ‘Field’

**Joint R&D Portfolio**

**Pharma**
- Chemistry IPR
- Toxicology
- Know How
- Assets in Kind
- Technology

**Pharma/Bio Gets**
- Private Sector Rights
- IPR outside ‘Field’
- PR Benefit
- HR Benefit
- Validation of Technology
Access and Delivery (A&D): A contractual balance of obligations and benefits

**MMV Input**
- $$$ mobilization of external support
- Advocacy
- Links to Global Fund PMI etc.
- Foreground IPR
- Need Profile
- Links to WHO, RBM and country policy makers
- Malaria specific Access Expertise, Advice (eg ADAC) and planning (GAPs)

**Public Gets**
- Affordable Drug Supply
- Private distribution in DEC
- Return on non DEC Sales
- Benefits of pooled procurement
- Available supplies
- Quality products
- Health Impact

**Pharma + Multinationals**
- Manufacturing
- QA
- Supply Chain & Delivery Know How
- Assets in Kind
- Liability Insurance

**Private Gets**
- Sales in non DEC
- IPR outside ‘Field’
- PR Benefit
- Guaranteed high sales volume
- Dependable clients

**Public**

**Joint**

**A&D**

**Private**
Access & Delivery Advisory Committee (ADAC – Non Statutory)

**Membres:** Awa Coll-Seck–Chair Executive Director RBM Chairperson

Members will be appointed from the following areas of expertise: Epidemiology, Regulatory, Quality Assurance/ PharmacoVigilence, Malaria Treatment & Coverage (Clinical), National Drug Policy Formulation, Finance, Pricing, Procurement / Supply Chain Logistics, Treatment / Local Delivery (Systems), Demand Creation / Marketing / Comms OR / Phase IV, Economics of Malaria / Willingness to Pay / Health Outcomes,

**Terms of Reference**

To advise on the development and implementation of product access plans to ensure timely and effective delivery of new anti-malarial drugs in malaria endemic countries

To provide more general advice & information to the CEO on appropriate strategies to achieve the MMV access and delivery goals
Expert Scientific Advisory Committee (ESAC - Statutory)


Terms of Reference  ESAC provides expert advice with respect to MMV’s portfolio, including project selection, transition and termination. The committee also guides MMV’s science staff in the improvement of its portfolio management guidelines, processes and structures. The ESAC supports MMV’s science staff in the interpretation of disease burden information for the formulation of ideal product profiles
MMV ESAC for 2005

Bob Snow; David Floyd; Dennis Schmatz; Tom Wellems; (Absent: Richard Auty); Zul Premji; Jurg Seiler Dave Mathews; David Roos; Kitima Yuthavong; Henrietta Ukwu; Win Gutteridge; Maria Paris; David Greenwood; George Aynilian
## Expanded ESAC for 2006

<table>
<thead>
<tr>
<th>Area</th>
<th>Functional Expertise</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>Overview</td>
<td><strong>Win Gutteridge (chair); Richard Auty</strong></td>
</tr>
<tr>
<td>R</td>
<td>Biology</td>
<td>David Roos; Meg Phillips**; Tom Wellems</td>
</tr>
<tr>
<td>R</td>
<td>Chemistry</td>
<td><strong>Dave Mathews; David Floyd; Vir Chauhan</strong></td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Transition</td>
<td><strong>Dennis Schmatz</strong></td>
</tr>
<tr>
<td>R&amp;D</td>
<td>CMC</td>
<td><strong>George Aynilian</strong></td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Toxicity</td>
<td><strong>Jurg Seiler</strong></td>
</tr>
<tr>
<td>R&amp;D</td>
<td>ADME</td>
<td>Bill Charman**</td>
</tr>
<tr>
<td>D</td>
<td>Clinical</td>
<td><strong>Kitima Yuthavong; Zul Premji; Maria Paris;</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Brian Greenwood</td>
</tr>
<tr>
<td>D</td>
<td>Regulatory</td>
<td><strong>Henrietta Ukwu</strong></td>
</tr>
<tr>
<td>D</td>
<td>Public health</td>
<td>Bob Snow*</td>
</tr>
</tbody>
</table>

**New for 2006**  Ex-industry
ESAC’s Main Activities

• Advise on selection for funding of discovery research and development project applications submitted to MMV on basis of periodic calls for LOIs (Letters of Interest)

• Carry out annual reviews of all projects in the MMV portfolio, including those in the Mini-portfolios, plus interim reviews of projects about which there are major causes for concern or which have reached a key milestone

• Carry out other tasks requested by CEO or CSO:
  • generation of documents eg on product profiles, research strategy, combinations
  • Actively participate in meetings eg Phase 3 Consensus
  • observing project groups in action
ESAC Terms of Appointment

- Can serve for up to 2 terms of 3 years each
- Standard confidentiality agreement signed
- Required annually to fill in a “links” document to indicate any direct or indirect involvement with any project being reviewed
- At discretion of the Chair and CSO, may be required to leave the meeting during a particular discussion
ESAC Mentor Programme

• A large number of malaria experts have served or are currently serving on ESAC

• Together they represent a valuable global malaria product R&D resource

• Almost all of them have agreed to be available for mentoring MMV projects

• The request for their help has to come from the project group and be approved by MMV

• MMV covers their travel and accommodation, and a small honorarium

• Eg, Dave Mathews is currently mentoring the Thai DHFR Project to transform their potent inhibitors of quadruple-mutant DHFR enzyme into drug-like molecules
MMV’s Objective: High Quality ACTS which are...

- APPROPRIATE
- AFFORDABLE
- ACCESSIBLE
Thank You

This girl does not know about global health policies or malaria control strategies. She cannot argue for the necessary actions and investments. We do and we can.

The clock is ticking for her and millions like her.