Science Supporting Access

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ASTMH
November 2007, Philadelphia, USA

Curing Malaria Together  www.mmv.org

Medicines for Malaria Venture
Outline

• MMV’s pipeline and development projects
• Why is MMV in access?
• Need for data-driven evidence base
• Conclusions
## MMV: Discovery and Development projects and now Delivery too

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Lead Opt</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
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<tbody>
<tr>
<td>Novartis 9 projects</td>
<td>OZ Next generation</td>
<td>Isoquine</td>
<td>Tafenoquine</td>
<td>iv artesunate</td>
<td>Chlorproguanil-dapsone-arteresunate</td>
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<td>GSK 3 projects</td>
<td>DHFR</td>
<td>MK 4815</td>
<td>Piperaquine (P)</td>
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<td>Artemether Lumerfantrine Dispersible</td>
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<td>Broad Genzyme 5 projects</td>
<td>Pyridone Back-ups</td>
<td>Pyridone 932121</td>
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<td>Dihydro-artemisinin-piperaquine</td>
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<td>Others 6 projects</td>
<td>Macrolides (Azithromycins)</td>
<td>DHODH</td>
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<td>Pyronaridine – Artesunate</td>
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Likelihood to Launch (CMR) 14% 27% 38% 72%
MMV works with partners in 33 countries

- Over 80 academic, industry and endemic country partners
- More than 600 scientists, clinicians, public health experts
Pipeline: timelines and attrition

Phase II as single agent comes first then Phase II as combination

Cumulative probability of completing pipeline is 1.3%
With approx 10 years of elapsed time

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<tr>
<td>Cum POS</td>
<td>30%</td>
<td>12%</td>
<td>7%</td>
<td>5%</td>
<td>4%</td>
<td>2%</td>
<td>1,5%</td>
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</table>
| Cumulative probability of completing pipeline is 1.3 %
With approx 10 years of elapsed time

Phase length (quarters)

- Explor.: 8
- Discov.: 20
- Precl.: 3
- Phase I: 2
- Comb.: 0
- Ph II: 3
- Ph III: 4
- Regul.: 1

Phase cost (k USD)

- Explor.: 250-500
- Discov.: 1.00
- Precl.: 2.000
- Phase I: 1.5-2.0
- Comb.: 6.00-9.00
- Ph II: 6.000/drug
- Ph III: 12.000

Source: MMV
Access = Delivering innovation for patients

- **Short term** – Launch up to four ACT products 2008/9
- **Medium term** – Expansion: severe malaria, *P. vivax*, and IPT (pregnancy and infants)
- **Medium term** – Pipeline: new molecules to replace artemisinins
- **Long term** – Increase mini-portfolios, innovative therapies and strategies for eradication
Four products supported by MMV likely to enter the market in next few years

- But the market often fails to deliver drugs to the poor
- Our products will only achieve health impact if available
  - at the **right** time
  - at the **right** price
  - at the **right** place
  - With the **right** information
...especially among the target population

**MMV’s Mission**
- To ensure *accelerated access* to and *responsible use* of MMV-supported products to achieve health impact
More studies needed to better profile late stage drugs for policy adoption

- Pivotal studies (Phase III) prove efficacy and safety in limited numbers and population in well-controlled studies
  - Not under real-world conditions
    - strict inclusion / exclusion criteria, hospital environment, run by global and national experts, etc.
  - Small numbers (1000-2000 patients)

Phase IIIb / IV studies
More studies needed to better profile late stage drugs for policy adoption

- Special populations
  - HIV AIDS; pregnancy, <5kgs, malnourished ……
- Calibration for age-weight groups
- Pharmacovigilance
- Effectiveness
- OTC rescheduling
- Safety databases
- Multiple first line treatment to protect pharmacophore

Many players involved but funding is an issue
Science is needed to support policy change

- Changing first line treatment
- Deploying multiple first-line treatments
- Ensuring responsible dispensing and use of antimalarials
- Safeguarding the therapeutic life of ACTs and delay onset of resistance
- Crowding out ineffective treatment
Need to close the cycle

Science Supporting adoption

R&D

Feedback to future R&D

Increased access to ACTs and New Drugs

MMV Activities

HEALTH IMPACT