MMV at a glance

- **Established in 1999** by WHO, 3 governments (UK, Switzerland, Netherlands), World Bank, Rockefeller Foundation and the IFPMA

- **Public-Private-Partnership, with a public health focus**
  - Swiss foundation, based in Geneva
  - Partners in almost 50 countries

- **A Virtual Organisation: 45 people**
  - (scientific team = 15, access team = 5)

- **Largest-ever pipeline of antimalarial drugs**
  - Over 50 projects ranging from Discovery stage to Phase III/IV

- **Success of Partnership Model has been proved**
  - 1 co-developed drug launched (Coartem-D)
  - 1 co-developed drug given positive opinion by the EMA (Eurartesim)
  - 1 co-developed drug under review by the EMA (Pyramax)
  - 1 drug WHO pre-qualified (Artesun)
# Global malaria portfolio, 3Q 2011

## Research

<table>
<thead>
<tr>
<th>Lead Opt</th>
<th>Preclinical</th>
<th>Translational</th>
<th>Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer/WHO/TDR</td>
<td>GNF156 Novartis</td>
<td>NITD609 Novartis</td>
<td>Azithromycin-chlooquine Pfizer</td>
</tr>
<tr>
<td>MSD</td>
<td>DSM265 (UTSW/STPHI/Monash)</td>
<td>CDRI 97/78 (Raj)</td>
<td>Pyronaridine-artesunate Shin Poong</td>
</tr>
<tr>
<td>GSK</td>
<td>Aminoindole Broad/Genzyme</td>
<td>DFO-Diror</td>
<td>Coartem® Novartis</td>
</tr>
<tr>
<td>USF/VAMC</td>
<td>AN3661 Anacor</td>
<td>New drug targets Pfizer/Nippon</td>
<td>ASAQ Winthrop Sanofi/DNDi</td>
</tr>
<tr>
<td>Drexel</td>
<td>MK4815 (Merck)</td>
<td>AQ13 Ibox</td>
<td>Artesunate for injection Guilin</td>
</tr>
<tr>
<td>USF/VAMC</td>
<td>P218 DHFR Biocyt/Genzyme</td>
<td>ASF976B</td>
<td>DHA-Piperquine Sigma-tau</td>
</tr>
<tr>
<td>Novartis</td>
<td>NPC-1161-B University of Mississippi</td>
<td>ART262D</td>
<td>MMV Non MMV</td>
</tr>
<tr>
<td>2 Projects</td>
<td>RKA182 Liverpool</td>
<td>ART262P</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ACT451840</td>
<td>ART262B</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BCX4945 Biocyt/Albert Einstein College of Medicine</td>
<td>ART262I</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SAR115242 Palumed</td>
<td>ART262L</td>
<td></td>
</tr>
</tbody>
</table>

## Registration

- Coartem® D Novartis
- ASAQ Winthrop Sanofi/DNDi
- Artesunate for injection Guilin
- DHA-Piperquine Sigma-tau
Uncomplicated *P. falciparum* malaria: Artemisinin-based combination therapies

**Past and current EDCTP/MMV partnerships:**
- Head-to-head comparison of 4 ACTs with U. d’Alessandro
- Longitudinal repeat doses study with 4 ACTs:
  - WANECAM study with Abdoulaye Djimde

**Future possible collaborations with EDCTP:**
- Longitudinal repeat doses studies to be conducted with the new drugs, probably in parallel with the phase III programme
- Clinical development of paediatric formulations

**Combinations:**
- Coartem-Dispersible (artemether/lumefantrine)
- Eurartesim (DHA/piperaquine)
- Pyramax (pyronaridine/artesunate)
- ASAQ (amodiaquine/artesunate)
Severe malaria: *Artesunate injectable*

- **Artesun (artesunate injectable) Guilin Pharma**
  MMV technical and financial support to gain WHO-Prequalification (05 November 2010)

- **Artesunate Injectable WRAIR/sigma-tau**
  EDCTP/MMV Study to evaluate a simplified intravenous artesunate regimen for severe malaria. Study conducted with Peter Kremsner and Sanjeev Krishna

**Future:** looking for collaboration with partners for setting-up a severe malaria registry
Malaria in pregnancy

Development of AZCQ with Pfizer in IPTp
Two studies on-going:
• Efficacy-PK in 166 2\textsuperscript{nd} & 3\textsuperscript{rd} trimester pregnant women (12)
• IPTp phase III study in 5000 pregnant women (750)

Discussion with U. d’Alessandro for a support of the ongoing EDCTP study with DHA/PQP in pregnant women

Future:
• Collaboration with MiP consortium to implement pregnancy registries for the new ACTs and the new non-ACTs
• Collaboration with EDCTP to develop the pregnancy indication for the new ACTs and the new non-ACTs
Drugs with gametocytocidal and hypnozoitocidal activity

**Tafenoquine**: in collaboration with GSK
- phase IIb/III study for the radical cure of *P. vivax* malaria started the last week of September
- Development of a point-of-care G-6-PD test in collaboration with GSK and PATH

**GNF156**: a new transmission blocking agent in collaboration with Novartis
- Phase I expected to start in 2012

**Possible future collaborations**:
- Transmission blocking studies with ACTs + tafenoquine then GNF156 in collaboration with EDCTP in Africa
- Studies for the radical cure of *P. vivax* malaria with EDCTP in East Africa (Ethiopia?)
Next generations of drugs in early clinical development

OZ439: Second generation synthetic endoperoxide
- MMV compound, without partner
- Currently in Phase IIa in Thailand
- Some of the phase IIb and/or III studies could be conducted in partnership with EDCTP

NITD609: New therapeutic class - Spiroindolone
- Drug developed in collaboration with Novartis
- Currently in Phase I in Australia
- Phase IIa will start in 2012 (Thailand, Bangladesh, Peru)
- Phase IIb/III, partnerships will be needed

Fosmidomycin/piperaquine:
- Discussions between EDCTP, MMV, Jomaa Pharma and David Hutchinson
THANK YOU