«Partnerships: The way to Successful Antimalarial Development»

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With Partners Bridging Therapeutic Gaps: The FACT Project to fight development of resistance
The FACT Project Concept
Increasing Options for Fixed Dose ACT’s

2002
- “WHO recommends in particular the use of drug combinations containing Artemisinin”
  - Artesunate-SP
  - Artemether-lumefantrine
  - Artesunate-amodiaquine
  - Artesunate-mefloquine
- 2006 WHO malaria treatment guidelines

- 2 fixed-dose ACTs
  - Easy to use:
    - fewer tablets in regimen
    - paediatric strengths
    - ensure drugs are taken together and in correct proportions
  - Affordable
  - Available as public good
The Blueprint of the ASMQ Tablet

- Quality components (AS, MQ, Excipients)
- Smallest possible size (Minimum excipients)
- Good aspect (Coating)
- Paediatric strengths; rapid disintegration in water
- Simple (1 or 2 tablets for 3 days)
- Stable (Process and Tropical conditions)
- Adequate biopharmaceutical properties
Artesunate-Mefloquine Fixed Dose Combination

Industrial Partners:
- Farmanguinhos
- Cipla

DNDi/TDR:
- scientific coordination & project management

Funding: EU’s INCODEV, France, Netherlands, Spain, UK, MSF
Artesunate/Mefloquine: Tablets & Dosing

**Low-Strength**
- MQ: 50 mg/tab
- AS: 25 mg/tab

**High-Strength**
- MQ: 200 mg/tab
- AS: 100 mg/tab

<table>
<thead>
<tr>
<th>Age</th>
<th>MQ # tabs/d</th>
<th>MQ mg/d</th>
<th>AS # tabs/d</th>
<th>AS mg/d</th>
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<tr>
<td>6-11m</td>
<td>1</td>
<td>50</td>
<td>1x25mg</td>
<td>25</td>
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<tr>
<td>1-5y</td>
<td>2</td>
<td>100</td>
<td>2x25mg</td>
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<td>200</td>
<td>1x100mg</td>
<td>100</td>
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<td>&gt;12y</td>
<td>2</td>
<td>400</td>
<td>2x100mg</td>
<td>200</td>
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Artesunate-Amodiaquine Fixed Dose Combination

Industrial Partners: Sanofi-Aventis

DNDi/TDR: scientific coordination & project management

Funding: EU’s INCODEV, France, Netherlands, Spain, UK, MSF
Simplified 3-Day Dose Regimen of AS/ AQ

NEW Fixed-dose AS/AQ
Artesunate/amodiaquine
3 dosage strengths available

- Infants (<8 kg)
  - AS: 25 mg
  - AQ: 67.5 mg

- Young Children (8-17 kg)
  - AS: 50 mg
  - AQ: 135 mg

- Children (17-35 kg)
  - AS: 100 mg
  - AQ: 270 mg

- Adults (>35 kg)
  - AS: 100 mg
  - AQ: 270 mg

Co-blistered non-fixed AS+AQ
Artesunate-amodiaquine
AS: 50 mg; AQ 153 mg
FACT Project
New Partnership for Implementation

**FACT FDC Products Licensors**
- UNITAID
- GF

**FACT FDC Products Implementers**
- NCP
- WHO/PAHO
- NGOs

**FACT FDC Products Manufacturers**
- sanofi-aventis
- Farmanguinhós
- Cipla

**FACT FDC Products Networks**
- INESS
- RAVEDRA
- WWARN

**FACT FDC Products Funders**
- UNITAID
- GF
FACT Project and Consortium
Acknowledging Partners

• **ASAQ**
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• **ASMQ**
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