MMV, SIGMA-TAU SYMPOSIUM

DIHYDROARTEMISININ/PIPERAQUINE: ADVANCING AND OPTIMIZING TREATMENT FOR UNCOMPLICATED MALARIA

WEDNESDAY, OCTOBER 5TH; 14:00 - 15:00 - ROOM 1
CENTRE DE CONVENCIONS INTERNATIONAL DE BARCELONA - BARCELONA - SPAIN

7TH EUROPEAN CONGRESS ON TROPICAL MEDICINE 2011 - BARCELONA

MMV
Medicines for Malaria Venture

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THE ROLE OF THE MMV-SIGMA TAU PARTNERSHIP IN DEVELOPING EURARTESIM AS A QUALITY ACT FOR MALARIA ENDEMIC COUNTRIES

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MMV Medicines for Malaria Venture

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The MMV Imperative

- In response to a virtually empty malaria drug pipeline, MMV was established in 1999 with a mission to discover, develop and deliver safe, effective and affordable antimalarial drugs

- As a not-for-profit PDP, MMV's goal is to cure and protect the vulnerable and help to ultimately eradicate malaria

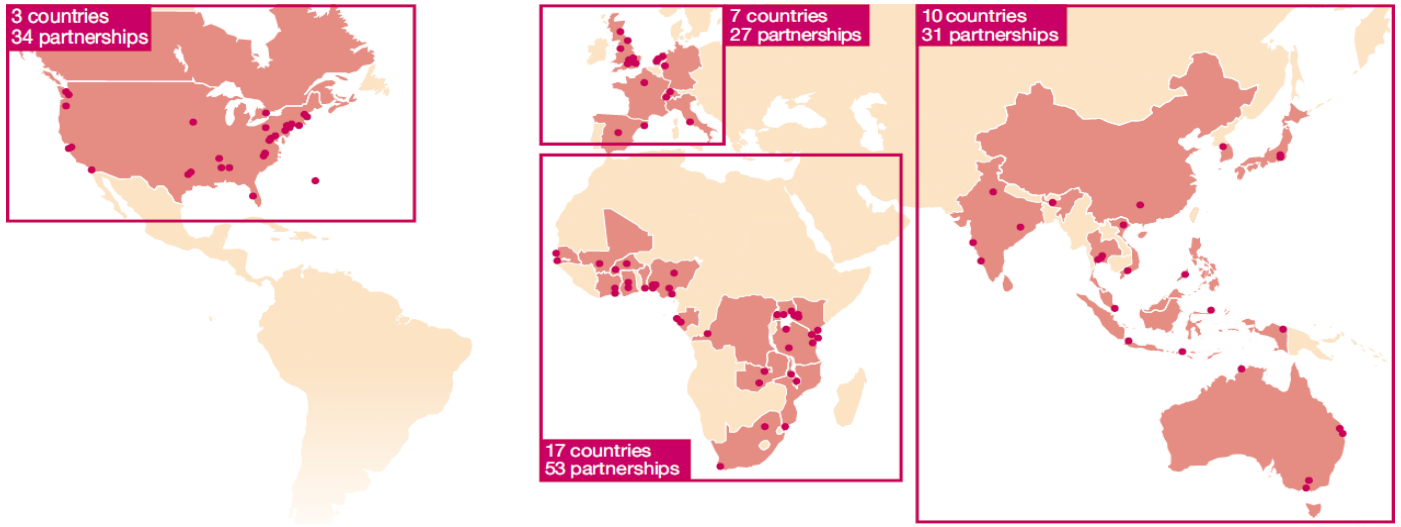
"From its outset, MMV has been a hard-nosed business venture with a compassionate, humanitarian heart." Margaret Chan, Director General, WHO

The MMV Approach: an effective PDP Model

"MMV shows how the market can work for the world's poorest people."
Melinda Gates

A successful public-private drug development partnership (PDP):

- A new way of doing business by using the potent synergies of over 150 partnerships in 43 countries
- Innovative and cost-effective
- Shares the risk of R&D investment across all sectors
- Leveraging private sector assets, creating a virtuous circle



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MMV Achievements

- First affordable, high quality pediatric ACT launched and saving lives – 72mn treatments delivered to 35 countries
- Two new ACTs submitted to EMA for regulatory approval
- WHO Prequalification of injectable artesunate
- Over 50 projects in antimalarial pipeline targeting new goal of malaria eradication
- Focused access global plan to ensure medicines reach those who need them most

"The contribution of MMV and its partners towards building an essential arsenal of new antimalarials is invaluable."

Awa Marie Coll-Seck, Roll Back Malaria Partnership (RBM)

MMV R&D Challenges

- Treatment of acute uncomplicated *P. falciparum* malaria
- Treatment of severe malaria
- Treatment for *P.vivax* malaria
- Treatments for children under 5 and pregnant women
- Medicines to block transmission
- Medicines to tackle resistance to first-line antimalarials
- Access to effective treatment for the poorest/ most vulnerable

… MMV's Solutions: R&D Portfolio 2011

Research		Translational			Development		
Lead Gen	Lead Opt	Preclinical	Phase I	Phase IIa	Phase IIb/III	Registration	Phase IV
Novartis miniportfolio	Novartis 2 Projects	MK 4815 (Merck)	NITD609 Novartis	OZ 439 (Monash/UNMC/ STI)	AZCQ Pfizer	DHA-Piperaquine Sigma-tau	Coartem®-D Novartis APPROVED
GSK miniportfolio	GSK 2 Projects	GNF156 Novartis	Tafenoquine GSK			Pyronaridine-AS Shin Poong/University of Iowa	ASAQ Winthrop sanofi aventis/DNDi APPROVED
Broad/Genzyme miniportfolio	Aminoindole Broad/Genzyme	AN3661 Anacor					IV artesunate Guilin APPROVED
Pfizer Screening	Aminopyridine UCT						
sanofi aventis Orthologue screen	Pyrazoles Drexel						
AstraZeneca Screening	Quinolones USF/ VAMC						
Kinases Monash	DHODH UTSW/UW/Monash						
Antimalarials St Jude/Rutgers							
Other Projects 12 Projects							

MMV has worked with partners to build the largest pipeline of antimalarials in history

Over 50 projects with regular review by MMV's Expert Scientific Advisory Committee (ESAC)

MMV's Access work: Assuring health impact

Access strategies supporting uptake of MMV's medicines

Health Impact

- Acceptance of Quality Treatments
- Expansion of Access to Treatment
- Measure and Monitor Impact

MMV & sigma-tau: Partners in developing safe, efficacious DHA-PQP to international GMP[1] standards

Sigma-tau-MMV partnership from 2004

- Sigma-tau: Founder's commitment
- Partnership scope includes joint product development, ongoing product enhancement and delivery

Dihydroartemisinin Piperaquine (DHA-PQP) Product Overview:

- One of five ACTs recommended by WHO Standard Treatment Guidelines for first-line treatment of uncomplicated falciparum malaria *(Strong recommendation, high quality evidence.)*
- First line treatment in four malaria endemic countries, 2nd line treatment in three additional countries
- Under EMA regulatory review. Not WHO-prequalified yet.
- **8 clinical trials, including Phase III in Asia and Africa**

[1] Good Manufacturing Practice

Future Path for DHA-PQP

Future Plans – post regulatory approval:

- Longitudinal study with European and Developing Countries Clinical Trials Partnership (EDCTP)
- INESS Safety and Effectiveness Studies in Ghana, Tanzania, Mozambique and Burkina Faso
- Paediatric dispersible formulation

Conflict of Interest Statement

- G. Jagoe is a member of MMV's Executive Management Group and has been involved in collaborations around the development of three MMV-supported drugs and in facilitating access to two MMV-supported drugs.
- MMV does not profit from any of its partnership alliances.
- G. Jagoe has not received compensation from any of the companies in the malaria disease area nor does he hold stocks or options in any of these companies.
- G. Jagoe did not receive travel assistance or honoraria for this presentation.
- G. Jagoe and MMV colleagues are solely responsible for the content of this presentation.

Thank You