AGENDA

Public Workshop—Clinical Trial Design Considerations for Malaria Drug Development

Thursday, June 30, 2016

ABSTRACT: The focus of this workshop is to discuss the scientific and regulatory challenges associated with anti-malarial drug development for the treatment of *P. falciparum* infection. This workshop will also focus on the use of parasite detection methods for differentiation between recrudescence and new infection in *P. falciparum* malaria clinical trials.

Time	***Topic***	***Speaker(s) and Affiliation***
7:30-8:30 AM	Registration	
8:30-8:45 AM	Opening Remarks	Ed Cox, MD, MPH *Director, Office of Antimicrobial Products (OAP), Center for Drug Evaluation and Research (CDER), FDA*
8:45-9:20 AM	Background on Malaria and Combination Anti-Malarial Drug Therapy	James McCarthy, MD *Senior Scientist, Queensland Institute of Medical Research (QIMR), Berghofer Medical Research Institute*

First Panel Session: Clinical Trial Design Considerations and Use of Multiple Drugs in Combination

Session Co-Chairs:

Sumathi Nambiar, MD, MPH, Director, Division of Anti-Infective Products (DAIP), OAP, CDER, FDA

James McCarthy, MD, Senior Scientist, Queensland Institute of Medical Research (QIMR), Berghofer Medical Research Institute

9:20-9:40 AM	FDA perspective: Scientific and Regulatory Issues Related to Anti-malarial Drug Development	Elizabeth O'Shaughnessy, MD *Medical Officer, DAIP, CDER, FDA*
9:40-10:00 AM	Controlled Human Malaria Infection Trials (CHMI)	James Kublin, MD, MPH *Clinical Associate Professor of Global Health, Executive Director of HIV Vaccine Trials Network, Fred Hutchinson Cancer Research Center, University of Washington*
10:00-10:20 AM	Induced Blood Stage Malaria: A Tool to Facilitate Development of Anti-Malarials	James McCarthy, MD *Senior Scientist, Queensland Institute of Medical Research (QIMR), Berghofer Medical Research Institute*
10:20-10:40 AM	Pharmacology Considerations for Combination Malaria Treatment	Jörg Möhrle, PhD, MBA *Vice President, Head of Translational Medicine, Research & Development, Medicines for Malaria Venture (MMV)*
10:40-10:50 AM	Morning Break	
10:50-12:00 PM	Moderated Panel Discussion (with Audience Q&A)	
	Panel Members: Tim Wells (MMV), James Kublin (University of Washington), James McCarthy (QIMR), Peter Weina (Walter Reed National Military Medical Center), Sean Murphy (University of Washington), Ingrid Felger (Swiss Tropical and Public Health Institute), Mike Proschan (National Institutes of Health), David Saunders (US Army Medical Materiel Development Activity), Matthew Laurens (University of Maryland School of Medicine), Bryan Smith (Clinical Network Services), Dakshina Chilukuri (FDA), Karen Higgins (FDA), Elizabeth O'Shaughnessy (FDA), Jörg Möhrle (MMV), Paul Arguin (Centers for Disease Control and Prevention)	

12:00-1:00 PM	**LUNCH**	
Second Panel Session: Current and Emerging Technologies: Role of Parasite Detection Methods in Malaria Clinical Trials ***Session Co-Chairs:*** ***Shukal Bala, PhD, Microbiologist, DAIP, OAP, CDER, FDA*** ***Ingrid Felger, PhD, Head of the Molecular Diagnostics Unit, Swiss Tropical and Public Health Institute (Swiss TPH)***		
1:00-1:20 PM	Molecular Detection, Quantification, Genotyping of *P. Falciparum* in *In Vivo* Drug Efficacy Trials	Ingrid Felger, PhD *Head of the Molecular Diagnostics Unit, Swiss Tropical and Public Health Institute (Swiss TPH)*
1:20-1:40 PM	Regulatory Considerations When Detection Methods are Used in Clinical Trials	Kalavati Suvarna, PhD *Microbiologist, DAIP, OAP, CDER, FDA*
1:40-2:00 PM	Recent Experience of Investigational Parasite Detection Methods in Controlled Human Malaria Infection (CHMI) Studies	Sean Murphy, MD, PhD *Assistant Professor in the Department of Laboratory Medicine, Assistant Director of the Clinical Microbiology Laboratory, University of Washington*
2:00-2:20 PM	Role of Malaria Detection Methods for Enrollment and Outcomes in Clinical Trials	David Saunders, MD, MPH *Clinical Pharmacologist and Internist, US Army Medical Materiel Development Activity*
2:20-2:30 PM	Afternoon Break	
2:30-3:50 PM	Moderated Panel Discussion (with Audience Q&A)	

	Panel Members: Tim Wells (MMV), James Kublin (University of Washington), James McCarthy (QIMR), Peter Weina (Walter Reed National Military Medical Center), Sean Murphy (University of Washington), Ingrid Felger (Swiss TPH), Mike Proschan (NIH), David Saunders (US Army Medical Materiel Development Activity), Matthew Laurens (University of Maryland School of Medicine), Bryan Smith (Clinical Network Services), Karen Higgins (FDA), Jörg Möhrle (MMV), Paul Arguin (CDC), Kalavati Suvarna (FDA), Noel Gerald (FDA), Rana Chattopadhyay (FDA)
3:50-4:00 PM	Closing Remarks

Speaker slides and other workshop material can be found at:
http://www.fda.gov/Drugs/NewsEvents/ucm490084.htm

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