

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Drug Evaluation and Research (CDER)**

***Antimicrobial Drugs Advisory Committee (AMDAC) Meeting***  
*FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)*  
*10903 New Hampshire Avenue, Silver Spring, Maryland*  
July 12, 2018

**AGENDA**

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*The committee will discuss new drug application (NDA) 210795, tafenoquine tablet, 150 mg, sponsored by GlaxoSmithKline Intellectual Property Development Ltd. England, for the proposed indication of the radical cure (prevention of relapse) of Plasmodium vivax malaria.*

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8:30 a.m.	Call to Order and Introduction of Committee	<b>Lindsey Baden, MD</b> Chairperson, AMDAC
8:40 a.m.	Conflict of Interest Statement	<b>Kalyani Bhatt, BS, MS</b> Acting Designated Federal Officer, AMDAC
8:45 a.m.	FDA Opening Remarks	<b>Yuliya Yasinskaya, MD</b> Clinical Team Leader Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:55 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>GlaxoSmithKline (GSK) Intellectual Property Development Ltd.</b>
	Introduction	<b>Dr. Joerg-Peter Kleim, PhD</b> Director Clinical Development and Medicines Development Leader, GSK
	Unmet Need	<b>Dr. Kevin Baird, PhD</b> Professor of Malariology Head of Unit, Eijkman Oxford Clinical Research Unit Jakarta, Indonesia
	Study Design and Clinical Efficacy	<b>Dr. Justin Green, MD</b> Director, Clinical Development and Project Physician Lead, GSK
	Safety Results	<b>Dr. Alison Webster, MD</b> Head of Clinical Development Global Health, GSK
	Clinical Perspective	<b>Dr. Richard (Ric) Price, MD</b> Professor of Tropical Medicine The University of Oxford Menzies School of Health Darwin, Australia

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**AGENDA (cont.)**

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10:25 a.m. Clarifying Questions

10:40 a.m. **BREAK**

10:50 a.m. **FDA PRESENTATIONS**

Presentation of Clinical Efficacy

**Xianbin Li, PhD**

Statistical Reviewer

Division of Biometrics IV

Office of Biostatistics

Office of Translational Sciences, CDER, FDA

Presentation of Clinical Safety

**Elizabeth O'Shaughnessy, MB, BCh**

Medical Officer

DAIP, OAP, OND, CDER, FDA

12:20 p.m. Clarifying Questions

12:35 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. **BREAK**

2:40 p.m. Questions to the Committee/Committee Discussion

4:00 p.m. **ADJOURNMENT**