

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

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the effectiveness of tafenoquine for the radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients 16 years of age and older?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed?

2. **VOTE:** Has the applicant provided adequate evidence of the safety of tafenoquine for the radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients 16 years of age and older?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed?