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
August 7, 2019

DRAFT QUESTIONS

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1. **VOTE:** Has the applicant provided substantial evidence of the safety and effectiveness of Descovy® for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually-acquired HIV-1 infection in men and transgendered women who have sex with men?

   a. If yes, please provide your rationale.

   b. If no, please provide your rationale and list what additional studies/trials are needed.

   c. Please provide any additional comments or thoughts on your vote.

2. **VOTE:** Do the data from the DISCOVER trial, in combination with the available pharmacokinetic data and other previous HIV-1 prevention trials with Truvada® in cisgender women, allow for the expansion of the Descovy® PrEP indication to include cisgender women?

   a. If yes, please provide your rationale.

   b. If no, please provide your rationale and list what additional studies/trials are needed. Also, comment on the trial designs that would be adequate to expand the indication.

   c. Please provide any additional comments or thoughts on your vote.

3. **DISCUSSION:** Please discuss whether the data from the DISCOVER trial are relevant to at-risk men who practice insertive vaginal sex with cisgender women.