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.