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

Antimicrobial Drugs Advisory Committee *(AMDAC) Meeting*
October 7, 2021

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the efficacy outcome in the phase 3 trial SHP620-303 and data from the phase 2 trial SHP620-202 and the overall risk-benefit assessment for maribavir. Include in the discussion the following:

    a. Population – narrow population with unmet medical need
    b. Trial design and limitations, including potential bias
    c. Primary efficacy outcome
    d. Results from the sensitivity and subgroup analyses
    e. Maribavir safety profile in comparison to other antivirals for cytomegalovirus (CMV)

2. **VOTE:** Is the overall benefit-risk assessment favorable for the use of maribavir for the treatment of transplant recipients with CMV infection and disease refractory to treatment and with genotypic resistance to ganciclovir, valganciclovir, foscarnet or cidofovir?

    a. If you voted "No", what additional information would be needed for the benefit-risk assessment to be favorable for the use of maribavir in this population?
        i. If a new clinical trial is recommended, please comment on trial design.

3. **VOTE:** Is the overall benefit-risk assessment favorable for the use of maribavir for the treatment of transplant recipients with CMV infection and disease refractory to treatment but without genotypic resistance to ganciclovir, valganciclovir, foscarnet or cidofovir?

    a. If you voted "No", what additional information would be needed for the benefit-risk assessment to be favorable for the use of maribavir in this population?
        i. If a new clinical trial is recommended, please comment on trial design.