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

Arthritis Advisory Committee (AAC) Meeting
May 6, 2021

DRAFT QUESTIONS

---

1. **DISCUSSION:** Discuss whether the results at Week 26 support a clinically meaningful benefit of avacopan. Include discussion of the following:
    a. Appropriateness of a primary non-inferiority (NI) comparison
    b. Use of additional non-study supplied glucocorticoids (GCs) in the avacopan group
    c. Lack of statistically significant superiority at Week 26

2. **DISCUSSION:** Discuss whether the results at Week 52 support a clinically meaningful benefit of avacopan. Include discussion of the following:
    a. Impact of the lack of maintenance therapy in the Rituximab (RTX) subgroup
    b. Discrepancies in Birmingham Vasculitis Activity Score (BVAS) remission responses as determined by Adjudication Committee vs. Investigators

3. **DISCUSSION:** Discuss whether the data support the use of avacopan as a steroid-sparing agent in anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV). Include discussion of the following:
    a. Use of additional non-study supplied GCs in the avacopan group
    b. Impact of a potential increase in GC exposures due to CYP3A4 inhibition by avacopan

4. **DISCUSSION:** Based on the data from the clinical program, discuss how avacopan, if approved, should be used in the treatment of AAV.

5. **VOTE:** Do the efficacy data support approval of avacopan for the treatment of adult patients with AAV (granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA))?
    a. If you voted "No", what data are needed?

6. **VOTE:** Is the safety profile of avacopan adequate to support approval of avacopan for the treatment of adult patients with AAV (GPA and MPA)?
    a. If you voted "No", what data are needed?

7. **VOTE:** Is the benefit-risk profile adequate to support approval of avacopan at the proposed dose of 30 mg twice daily for the treatment of adult patients with AAV (GPA and MPA)?
    a. If you voted "No", what further data are needed?