

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

*Arthritis Advisory Committee (AAC) Meeting*  
May 6, 2021

**QUESTIONS**

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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?