

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

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

**DRAFT AGENDA**

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*The committee will discuss New Drug Application (NDA) 214487, for avacopan oral capsules, submitted by ChemoCentryx, Inc., for the treatment of Anti-Neutrophil Cytoplasmic Antibody (ANCA)-associated Vasculitis.*

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| 10:00 a.m. | Call to Order  | <b>Mara Becker, MD, MSCE</b><br>Chairperson, AAC  |
| 10:10 a.m. | Introduction of Committee and Conflict of Interest Statement | <b>Moon Hee V. Choi, PharmD</b><br>Acting Designated Federal Officer, AAC   |
| 10:15 a.m. | FDA Opening Remarks  | <b>Rachel L. Glaser, MD</b><br>Clinical Team Leader<br>Division of Rheumatology and Transplant Medicine<br>Office of Immunology and Inflammation<br>Office of New Drugs, CDER, FDA  |
| 10:20 a.m. | <b>APPLICANT PRESENTATIONS</b>                               | <b>ChemoCentryx, Inc.</b>   |
|            | Introduction   | <b>Pirow Bekker, MD, PhD</b><br>Clinical Lead<br>Avacopan Clinical Development Program<br>ChemoCentryx, Inc.  |
|            | Efficacy   | <b>Peter Merkel, MD, MPH</b><br>Chief, Division of Rheumatology<br>Director, Penn Vasculitis Center<br>University of Pennsylvania   |
|            | Safety   | <b>David Jayne, MD</b><br>Professor of Clinical Autoimmunity<br>University of Cambridge, United Kingdom<br>Director, Vasculitis and Lupus Service<br>Addenbrooke's Hospital<br>President, European Vasculitis Society (EUVAS) |
|            |  | <b>Pirow Bekker, MD, PhD</b>  |
| 10:50 a.m. | Clarifying Questions for Applicant                           |   |

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11:20 a.m. **FDA PRESENTATIONS**

FDA Summary Presentation

**Rachel L. Glaser, MD**

11:50 a.m. Clarifying questions for FDA

12:20 p.m. **LUNCH BREAK**

1:15 p.m. **OPEN PUBLIC HEARING**

2:15 p.m. Charge to the Committee

**Rachel L. Glaser, MD**

2:20 p.m. Questions to the Committee/Committee  
Discussion

4:15 p.m. **ADJOURNMENT**

**DRAFT**