

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

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

**DRAFT AGENDA**

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*The committee will discuss new drug application (NDA) 215596, for maribavir oral tablets, submitted by Takeda Pharmaceuticals USA, Inc., for the treatment of adults with post-transplant cytomegalovirus infection and/or disease, including infections resistant and/or refractory to ganciclovir, valganciclovir, cidofovir, or foscarnet.*

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9:00 a.m.	Call to Order	<b>Lindsey R. Baden, MD</b> Chairperson, AMDAC
9:10 a.m.	Conflict of Interest Statement and Introduction of Committee	<b>Moon Hee V. Choi, PharmD</b> Acting Designated Federal Officer, AMDAC
9:15 a.m.	FDA Opening Remarks	<b>Debra Birnkrant, MD</b> Director Division of Antivirals (DAV) Office of Infectious Disease (OID) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Takeda Pharmaceuticals USA, Inc.</b>
	Introduction	<b>Michael Cronin, PharmD</b> Director, Global Regulatory Lead Takeda
	Overview of Post-Transplant Resistant/Refractory CMC Infection and Unmet Needs	<b>Camille Kotton, MD</b> Clinical Director of Transplant and Immunocompromised Host Infectious Diseases Massachusetts General Hospital
	Maribavir Clinical Efficacy	<b>Martha Fournier, MD</b> Executive Director Global Clinical Development Lead Takeda
	Maribavir Clinical Safety	<b>Adedeji Adefuye, MD, MPH, FRIPH, FRSPH</b> Vice President Head of Medical Safety, Rare Diseases Takeda

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**DRAFT AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

Clinical Perspective

**Robin Avery, MD**  
Professor of Medicine  
Division of Infectious Disease  
Johns Hopkins

10:20 a.m. Clarifying Questions

10:40 a.m. **BREAK**

10:50 a.m. **FDA PRESENTATIONS**

Background; Efficacy

**Andreas Pikis, MD**  
Medical Officer  
DAV, OID, OND, CDER, FDA

Virology

**Takashi Komatsu, PhD, RAC**  
Clinical Virology Reviewer  
DAV, OID, OND, CDER, FDA

Safety; Conclusions

**Andreas Pikis, MD**

11:45 a.m. Clarifying Questions

12:05 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Charge to the Committee

**Debra Birnkrant, MD**

2:05 p.m. Questions to the Committee/Committee Discussion

3:30 p.m. **BREAK**

3:40 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**