

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting

October 7, 2021

AGENDA

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.

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

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

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

AGENDA (cont.)

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 (cont.)

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