

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

Antiviral Drugs Advisory Committee (AVDAC) Meeting

DoubleTree by Hilton Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, Maryland
May 11, 2012

AGENDA

The committee will discuss a new drug application (NDA) 203100, for a fixed-dose combination tablet of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, submitted by Gilead Sciences, Inc. The application proposes an indication for the treatment of HIV-1 infection in adults who are antiretroviral naïve or have no known substitutions associated with resistance to the individual components.

8:00 a.m.	Call to Order and Introduction of Committee	Yoshihiko Murata, M.D., Ph.D. Acting Chairperson, AVDAC
8:05 a.m.	Conflict of Interest Statement	Yvette Waples, Pharm.D. Acting Designated Federal Officer, AVDAC
8:15 a.m.	Opening Remarks	Linda Lewis, M.D. Medical Team Leader Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	SPONSOR PRESENTATIONS	Gilead Sciences, Inc.
	Introduction	Andrew Cheng, M.D., Ph.D. Senior Vice President Clinical Research and Development Operations Gilead Sciences, Inc.
	Early Clinical Development	Brian Kearney, Pharm.D. Senior Director Clinical Pharmacology Gilead Sciences, Inc.
	Clinical Program, Efficacy and Safety	Javier Szwarcberg, M.D., MPH Senior Director Clinical Research Gilead Sciences, Inc.
	Benefit/Risk	Andrew Cheng, M.D., Ph.D.
10:00 a.m.	Clarifying Questions from Committee	

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AGENDA (cont.)

10:30 a.m. **BREAK**

10:45 a.m. **FDA PRESENTATION**

Elvitegravir/Cobicistat/Emtricitabine/
Tenofovir Disoproxil Fumarate
(EVG/COBI/FTC/TDF)
Fixed Dose Combination

Adam Sherwat, M.D.
Medical Officer
DAVP, OAP, OND, CDER, FDA

11:30 a.m. Clarifying Questions from the Committee

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Charge to the Committee

Linda Lewis, M.D.

2:15 p.m. Questions to the Committee and Committee Discussion

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

3:45 p.m. Questions to the Committee and Committee Discussion

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