

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

***Antiviral Drugs Advisory Committee (AVDAC) Meeting***  
Sheraton Silver Spring Hotel, Cypress Ballroom  
8777 Georgia Avenue, Silver Spring, Maryland  
October 24, 2013

**AGENDA**

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*The committee will discuss a New Drug Application (NDA) 205123, simeprevir (a hepatitis C virus protease inhibitor), manufactured by Janssen Pharmaceutical Co., with a proposed indication for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin (two medicines approved to treat chronic hepatitis C) in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve or who have failed previous interferon therapy (pegylated or non-pegylated) with or without ribavirin. Compensated liver disease is a stage in which the liver is damaged but maintains ability to function.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Yoshihiko Murata, M.D., Ph.D.</b> Chairperson, AVDAC
8:15 a.m.	Conflict of Interest Statement	<b>Karen Abraham-Burrell, Pharm.D.</b> Designated Federal Officer, AVDAC
8:30 a.m.	FDA Introductory Remarks	<b>Debra Birnkrant, M.D.</b> Director, Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	<b>SPONSOR PRESENTATIONS</b>	<b>Janssen Pharmaceutical Company</b>
	Opening Remarks	<b>Gaston Picchio, Ph.D.</b> Vice President, Hepatitis Disease Area Janssen
	Evolving Risks and Benefits of HCV Treatment in the Era of Direct-Acting Antivirals	<b>Nid Afdal, M.D.</b> Chief of Hepatology Beth Israel Deaconess Medical Center
	Overview	<b>Katia Boven, M.D.</b> Medical Department Head, Infectious Diseases and Vaccines Janssen
	Efficacy	<b>Maria Beumont-Mauviel, M.D.</b> Senior Director, Medical Team Lead SMV Janssen
	Virology	<b>Oliver Lenz, Ph.D.</b> Scientific Director, Clinical Virology Lead SMV Janssen

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**AGENDA (cont.)**

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Safety

**Wolfgang Jessner, M.D.**  
Medical Director, Trial Physician SMV  
Janssen

Recommendations for Treatment  
Management with Simeprevir and PR

**Gaston Picchio, Ph.D.**  
Vice President, Hepatitis Disease Area  
Janssen

10:15 a.m. Clarifying Questions

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

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

Simeprevir - Summary of FDA Review

**Adam Sherwat, M.D.**  
Medical Officer  
Division of Antiviral Products (DAVP)  
Office of Antimicrobial Products (OAP)  
Office of New Drugs (OND), CDER, FDA

Highlights of Simeprevir Clinical  
Pharmacology

**Leslie W. Chinn, Ph.D.**  
Clinical Pharmacology Reviewer  
Division of Clinical Pharmacology IV  
Office of Clinical Pharmacology (OCP)  
Office of Translational Sciences (OTS)  
CDER, FDA

11:45 a.m. Clarifying Questions

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

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion

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