

**Summary Minutes of the  
Anti-Infective Drugs Advisory Committee  
November 18-20, 2008**

**Location: Holiday Inn, The Ballrooms, 10000 Baltimore Avenue, College Park, MD**

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information office.

These summary minutes for the November 18-20, 2008, Meeting of the Anti-Infective Drugs Advisory Committee of the Food and Drug Administration were approved on December 9, 2008.

I certify that I attended the November 18-20, 2008, meeting of the Anti-Infective Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

\_\_\_\_\_/s/\_\_\_\_\_  
Janie Kim, Pharm.D.  
Designated Federal Official, AIDAC

\_\_\_\_\_/s/\_\_\_\_\_  
L. Barth Reller, M.D.  
Acting Committee Chair

**Meeting of the Anti-Infective Drugs Advisory Committee  
November 19, 2008 (Morning session)**

The Anti-Infective Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met on November 18, 2008 at the Holiday Inn Ballroom, 10000 Baltimore Ave, College Park, Maryland. Prior to the meeting, members and invited consultants were provided copies of the background material from the FDA and the sponsor. The meeting was called to order by L. Barth Reller, M.D. (Acting Committee Chair); the conflict of interest statement was read into the record by Janie Kim, Pharm.D. (Designated Federal Official). There were approximately \_\_\_ persons in attendance.

**Issue:** The committee will discuss NDA 022-110 Telavancin, Theravance, Inc. and Astellas Pharma, Inc., proposed indication for the treatment of complicated skin and skin structure infection (cSSSI).

**Attendance:**

**Anti-Infective Drug Advisory Committee Members Present (Voting):** Dean Follmann, Ph.D., Kathleen Gutierrez, M.D., Carol Kauffman, M.D.

**Non-voting Participant:**

John Rex, M.D. (Industry Representative)

**Special Government Employee Consultants Present (Voting):**

W. Kemper Alston, M.D., Henry Black, M.D., Alan Cross, M.D., Thomas Fleming, Ph.D., Matthew Goetz, M.D., Joan Hilton, Sc.D., Peter Katona, M.D., James Leggett, M.D., Timothy S. Lesar, Pharm.D., Arthur Levin, M.P.H. (Consumer representative), Philip Mirkes, Ph.D., Lewis Nelson, M.D., Emil Paganini, M.D., Edward Septimus, M.D., Mary Alice Smith, Ph.D., James Steckelberg, M.D., Jeanine Thomas (Patient representative), Melvin Weinstein, M.D.

**Regular Government Employee Consultants Present (Voting):**

John Bennett, M.D., Janet Cragan, M.D., Jeffrey Kopp, M.D., Michael Shelby, Ph.D.

**Anti-Infective Drugs Advisory Committee Members Not Present:**

Susan Rehm, M.D., Margo Smith, M.D., Gregory Townsend, M.D., Allan Tunkel, M.D., Ph.D., Annie Wong-Beringer, Pharm.D., Bernhard Wiedermann, M.D.

**FDA Participants (Non-Voting):** Edward Cox, M.D., M.P.H., Katherine Laessig, M.D., Sumathi Nambiar, M.D., M.P.H., Janice Pohlman, M.D., M.P.H., Zhou Chen, M.D., Ph.D.

**Designated Federal Official:**

Janie Kim, Pharm.D.

**Open Public Hearing Speaker:**

None.

*The agenda was as follows:*

Call to Order and Introductions	<b>L. Barth Reller, M.D.</b> Acting Chair
Conflict of Interest Statement	<b>Janie Kim, Pharm.D.</b> Designated Federal Official

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**Introductory Remarks**

Katherine Laessig, M.D., Deputy Director  
Division of Anti-infective and Ophthalmology Products (DAIOP)  
Office of Antimicrobial Products (OAP)

**Sponsor's Presentation:**

The Growing Need for Agents to Treat cSSSI

The Telavancin Program in cSSSI

A Benefit:Risk Assessment of Telavancin for cSSSI

**Theravance, Inc.**

G. Ralph Corey, MD, Duke University

Steven Barriere, Pharm.D., Theravance, Inc.  
Rebecca Coleman, Pharm.D., Theravance, Inc.  
Anthony Scialli, MD, Ph.D., Tetra Tech Sciences

Louis Saravolatz, M.D., St. John Hospital, Detroit

**FDA Presentation**

Efficacy and Safety of Telavancin

Pharmacology/Toxicology

Telavancin use during pregnancy: a maternal health perspective

Overview of Risk Management and Considerations for Telavancin

Questions to the Presenters

Open Public Hearing

Questions to the AIDAC and AIDAC Discussion

Adjourn

Janice Pohlman, M.D., M.P.H., Acting Lead Medical Officer, DAIOP, OAP

Zhou Chen, MD, Ph.D., Pharmacologist, DAIOP, OAP

Karen Feibus, M.D., Medical Team Leader, Maternal Health Team Office of New Drugs, Center for Drug Evaluation and Research (CDER)

Suzanne Berkman, Pharm.D., Senior Drug Risk Management Analyst Division of Risk Management, Office of Surveillance and Epidemiology

***Questions to the committee:***

1. Do the data presented demonstrate the safety and effectiveness of telavancin for the treatment of cSSSI? Please vote Yes/No.

***Vote :***                    ***Yes= 21***      ***No = 5***      ***Abstain = 0***

- If your answer is Yes, are there specific issues that should be addressed in labeling?

**Discussion**

*Committee members felt that renal toxicity, QTc prolongation, and teratogenic effects of the drug should be addressed in labeling.*

- Would you recommend any post-marketing studies to further evaluate nephrotoxicity?

**Discussion**

*Committee members felt that post-marketing studies to further evaluate nephrotoxicity are warranted with particular attention paid to situations of rising creatinine clearance levels, repeat and/or prolonged use of the drug, and mortality data.*

- If your answer is No, what additional data/trials are needed?

*Committee members who voted no did not specifically comment on this question.*

2. Are there clinical situations when the benefits of telavancin use in a pregnant woman would outweigh the risks? Please vote Yes/No.

**Vote :**            **Yes= 18      No = 5      Abstain = 3**

- If your answer is Yes, please describe those situations.

Discussion

*Committee members commented on situations of rare, life-threatening, multi-drug-resistant strains of cSSSI.*

3. Is a risk management strategy needed to prevent unintended use in pregnant women? Please vote Yes/No.

**Vote :**            **Yes= 25      No = 1      Abstain = 0**

- If your answer is Yes, what elements should be included?

Discussion

*Committee members considered the following risk management strategies:*

- *Pregnancy tests prior to initiation of therapy*
- *Partnerships with hospitals to prospectively collect data on use of the drug in pregnant women*
- *Pregnancy registries to track the outcomes of use in pregnant women*
- *Educate women on the risks associated with use of the drug during pregnancy*

**Please see the transcript for detailed discussion.**

The session adjourned @ approximately 12:45 p.m.