

**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 (Afternoon 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 022-153, oritavancin, Targanta Therapeutics Corp., proposed 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.

Special Government Employee Consultants Present (Voting):

W. Kemper Alston, 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), Lewis Nelson, M.D., Edward Septimus, M.D., Jeanine Thomas (Patient representative), Melvin Weinstein, M.D.

Regular Government Employee Consultants Present (Voting):

John Bennett, M.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, John Rex, M.D. (Non-voting Industry Representative)

FDA Participants (Non-Voting): Edward Cox, M.D., M.P.H., Katherine Laessig, M.D., Nasim Moledina, M.D., John Alexander, M.D., M.P.H., Thamban Valappil, Ph.D.

Designated Federal Official:

Janie Kim, Pharm.D.

Open Public Hearing Speaker:

None.

The agenda was as follows:

Call to Order and Introductions **L. Barth Reller, M.D.**
Acting Chair

Conflict of Interest Statement **Janie Kim, Pharm.D.**
Designated Federal Official

Sponsor's Presentation:

Targanta Therapeutics Corporation
Dr. Thomas Parr, Chief Scientific Officer
Dr. Pierre Etienne, Chief Development Officer
Dr. Susan Moriarty, Senior Director of Medical Affairs

FDA Presentation

Nasim Moledina, M.D.

Questions to the Presenters

Open Public Hearing

Questions to the AIDAC
and AIDAC Discussion

Adjourn

Questions to the committee:

1. Does study ARRI independently provide evidence of the effectiveness of oritavancin for cSSSI?
Please vote Yes/No and in your response, discuss the following:

Vote : ***Yes= 11 No = 6 Abstain = 1***

The primary outcome, 95% and 99.875% CI for the study

Discussion

Committee members who voted “yes” felt that the overall weight of evidence suggested that the drug was effective for cSSSI but several would have voted differently if the question had been about MRSA.

Outcomes for patients with known baseline pathogens, particularly MRSA

Discussion

Committee members felt that the data did not support efficacy for MRSA.

2. Does study ARRD independently provide evidence of the effectiveness of oritavancin for cSSSI?
Please vote Yes/No and in your response, discuss the following:

Vote : ***Yes= 8 No = 10 Abstain = 0***

The primary outcome and 97.5% CI for the study

Discussion

Committee members who voted “no” felt that ARRD is basically an underpowered, phase II, dose finding study and could not be counted as one of two adequate, well controlled trials.

Committee members who voted “yes” felt that the company met the non-inferiority margin that it was designed to do at a time when MRSA was not as prevalent as it is now.

The weight-based dosing regimen used in study ARRD

Discussion

Committee members felt that data that was relevant was from the 3 mg/kg dosing arm.

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

Vote : ***Yes= 8 No = 10 Abstain = 0***

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

Committee members did not address this portion of the question.

If your answer is no, what additional data/studies are needed?

Committee members felt that at least one additional study using a single appropriate dose should be performed in the MRSA population.

Please see the transcript for detailed discussion.
The session adjourned @ approximately 5:30 p.m.