ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEETING (68th)

Center for Drug Evaluation and Research, Food and Drug Administration
Marriott Washingtonian Center, Gaithersburg, MD

March 24, 2000

OPEN SESSION

**Issue:** New Drug Applications (NDA) 21-130, Zyvox® (linezolid) Tablets; NDA 21-131, Zyvox® (linezolid injection) for Injection; and NDA 21-132, Zyvox® (linezolid oral suspension) Oral Suspension.

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<th>TIME</th>
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| 8:30 | Call to Order | Barth L. Reller, M.D., Chairman  
Conflict of Interest Statement | Kimberly L. Topper, Executive Secretary  
Gary Chikami, M.D., Director |
| 8:35 | Opening Remarks | Division of Anti-Infective Drug Products,  
Office of Drug Evaluation IV, FDA |
| 8:45 | Applicant Presentation | Pharmacia & Upjohn  
Introduction and Microbiology: | Gary Tarpley, Ph.D.  
Vice President, Discovery Research |
|  | Clinical Pharmacology and Clinical Trial Results | Barry Hafkin, M.D.,  
Director, Clinical Research |
|  | Early Pediatric Studies: | Donald Anderson, M.D.,  
Vice President and Chief Scientific Officer, Research and Development |
| 10:15 | Committee Q&A |  |
| 10:30 | BREAK |  |
| 10:45 | FDA Presentation | David Ross, M.D., Ph.D.  
Medical Officer |
|  |  | Division of Anti-Infective Drug Products,  
Office of Drug Evaluation IV, FDA |
| 12:00 | Committee Q&A |  |
| 12:15 | LUNCH |  |
| 1:30 | Open Public Hearing |  |
| 2:30 | Committee Discussion |  |
| 4:00 | BREAK |  |
| 4:15 | Committee Discussion and Vote |  |
| 5:30 | Adjourn |  |
QUESTIONS

1) Community-acquired pneumonia (CAP)
   a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with CAP?

   b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of CAP due to:
      i) Methicillin-resistant Staphylococcus aureus (MRSA)
      ii) Penicillin-resistant Streptococcus pneumoniae (PRSP)

2) Hospital-acquired pneumonia (HAP)
   a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with HAP?

   b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of HAP due to:
      i) MRSA
      ii) PRSP

3) Uncomplicated skin and skin structure infections (uSSSI)
   a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with uSSSI?

   b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of uSSSI due to:
      i) MRSA

4) Complicated skin and skin structure infections (cSSSI)
   a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with cSSSI?

   b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of cSSSI due to:
      i) MRSA

5) Infections due to vancomycin-resistant enterococci (VRE)
   a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with infections due to VRE?

   b) What additional study(ies), if any, would the committee recommend?
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

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February 24, 2000
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEETING (68th)

Center for Drug Evaluation and Research, Food and Drug Administration
Marriott Washingtonian Center, Gaithersburg, MD

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