

Anti-Infective Drugs Advisory Committee
Food and Drug Administration
Center for Drug Evaluation and Research

Holiday Inn, The Ballrooms
8120 Wisconsin Ave., Bethesda, MD. 20879

New Drug Applications (NDA) 21-144
for Ketek™ (telithromycin), Adventis Pharmaceuticals Inc.

Agenda - April 26, 2001

- 8:00 Call to Order, Introductions** Lyman Barth Reller, M.D., Chair
- 8:05 Meeting Statement** Thomas H. Perez, M.P.H., Executive Secretary
- 8:10 Opening Remarks** Dianne Murphy, M.D., Director, ODE IV
Janice Soreth, M.D., Acting Director, Division of Anti-Infective Drug Products
- 8:15 Cardiology Presentation** Jeremy Ruskin, M.D.
- 9:00 FDA Post-Marketing Review of Torsades de Pointe** Douglas Shaffer, M.D.
- 9:20 Break**
- 9:35 Adventis Presentation:**
Introduction - - - - Mindell Seidlin, M.D., Vice President, Clinical Development, AntiInfectives
Microbiology - - - - Andre Bryskier, M.D., Senior Director, Clinical Microbiology
Human Pharmacology - - - Vijay Bhargava, Ph.D., Senior Director, Drug Metabolism and Pharmacokinetics
Clinical Efficacy & Safety - - Bruno Leroy, M.D., Senior Director, Clinical Development, AntiInfectives
ECG Analysis - - - Claude Benedict, M.D., Senior Vice President, Preclinical and Early Clinical Development
Conclutions - - - - Mindell Seidlin, M.D., Vice President, Clinical Development, AntiInfectives
- 11:15 Question and Answer Session**
- 11:45 Lunch**
- 12:45 FDA Presentation:**
Clinical Efficacy - - - - - George Rochester, Ph.D., Senior Statistician, Division of Biometrics III
Resistant S. pneumoniae - - Alma Davidson, M.D., Medical Officer, Division of AntiInfective Drug Products
General Safety Profile - - - - David Ross, M.D., Ph.D., Team Leader, Division of AntiInfective Drug Products
Hepatic Effects - Edward Cox, M.D., Medical Officer, Div. of Special Pathogens & Immunologic Drug Products
- 1:55 Drug- Induced Liver Disease** - - - Zachary D. Goodman, M.D., Armed Forces Institute of Pathology
- 2:15 FDA Presentation Summary** - - - - David Ross, M.D.
- 2:25 Question and Answer Session**
- 2:40 Break**
- 2:55 Open Public Hearing**
- 3:55 Discussion of Questions and Vote**
- 6:00 Adjourn**