

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
August 7, 2018

DRAFT AGENDA

The committee will discuss new drug application (NDA) 207356, amikacin liposome inhalation suspension, sponsored by Inmed, Inc., for the proposed indication of treatment of nontuberculous mycobacterial (NTM) lung disease caused by Mycobacterium avium Complex (MAC) in adults as part of a combination antibacterial drug regimen.

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| 8:30 a.m. | Call to Order and Introduction of Committee | Lindsey R. Baden, MD Chairperson, AMDAC |
| 8:40 a.m. | Conflict of Interest Statement | Lauren D. Tesh, PharmD, BCPS Designated Federal Officer, AMDAC |
| 8:45 a.m. | FDA Opening Remarks | Sumathi Nambiar MD, MPH Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA |
| 8:55 a.m. | APPLICANT PRESENTATIONS | Inmed, Inc. |
| | Introduction | Paul Streck, MD Chief Medical Officer Inmed, Inc. |
| | Unmet Need | Shannon Kasperbauer, MD Associate Professor Department of Medicine Division of Mycobacterial and Respiratory Infections National Jewish Health |
| | Efficacy | Eugene Sullivan, MD Chief Product Strategy Officer Inmed, Inc. |
| | Safety | Peter Sallstig, MD Vice President, Clinical Development Inmed, Inc. |
| | Clinical Perspective | David Griffith, MD Professor of Medicine University of Texas Health Science Center at Tyler |
| 10:25 a.m. | Clarifying Questions | |

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DRAFT AGENDA (cont.)

10:40 a.m. **BREAK**

10:50 a.m. **FDA PRESENTATIONS**

Presentation of Clinical Efficacy

Peter Kim, MD, MS
Clinical Team Leader
DAIP, OAP, OND, CDER, FDA

Presentation of Clinical Safety

Hiwot Hiruy, MD, PhD
Medical Officer
DAIP, OAP, OND, CDER, FDA

12:20 p.m. Clarifying Questions

12:35 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. **BREAK**

2:40 p.m. Questions to the Committee/Committee Discussion

4:00 p.m. **ADJOURNMENT**