



AGENDA

FDA Public Workshop

Development of Inhaled Antibacterial Treatments for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis

June 27, 2018

FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Great Room, Silver Spring, MD 20993.

<i>Time</i>	<i>Topic</i>	<i>Speaker(s) and Affiliation</i>
7:30-8:30 AM	Registration	
8:30 AM-8:45 AM	Introductory Remarks and Panel Introduction	Ed Cox, MD, MPH, FDA
8:45 AM-9:15 AM	Cross-Cutting Device and Human Factors Challenges and Considerations	Quynh Nguyen, MS, FDA Deepika Lakhani, PhD, FDA
Session 1: Cystic Fibrosis: Current Landscape, Challenges and Case Studies		
Session Co-Chairs: Sumathi Nambiar (FDA), Patrick Flume (Medical University of South Carolina)		
9:15 AM-9:30 AM	Inhaled Antimicrobial Therapy for Cystic Fibrosis: A Regulatory Evolution	Shrimant Mishra, MD, FDA
9:30 AM-10:00 AM	Inhaled Antibiotics in Cystic Fibrosis: Current State and Future Considerations	David Nichols, MD
10:00 AM-10:15 AM	Patient Speaker/Patient Perspective	Chip Hawkins
10:15 AM-10:30 AM	<i>BREAK</i>	
Cystic Fibrosis Trial Designs of the Future: Case Studies for CF Infection		



10:30 AM-12:00 PM	Prevention of Exacerbations/ Management of CF Patients Chronically Infected with <i>Pseudomonas aeruginosa</i> (5-7 minutes) <ul style="list-style-type: none"> Moderated Panel Discussion (~40 minutes) 	Maria Allende, MD, FDA
	Overview and Issues: Developing Inhalational Products for the Treatment of Chronic MRSA Infection in Cystic Fibrosis (5-7 minutes) <ul style="list-style-type: none"> Moderated Panel Discussion (~40 minutes) 	Shrimant Mishra, MD, FDA
12:00 PM-1:00 PM	LUNCH	
1:00 PM-1:20 PM	<i>Formal Public Comments</i> <ul style="list-style-type: none"> Amy Leitman (NTM Info and Research) Mary Kitlowski Cara Pasquale (COPD Foundation) 	
Session 2: Non-CF Bronchiectasis: Current Landscape, Challenges and Case Study		
Session Co-Chairs: Tom Smith (FDA), Anne O'Donnell (Georgetown University)		
1:20 PM-1:25 PM	Non-Cystic Fibrosis Bronchiectasis: Historical Perspective of Product Development	Thomas Smith, MD, FDA
1:25 PM-1:55 PM	Care of the Bronchiectasis Patient: Current State	Greg Tino, MD
1:55 PM-2:10 PM	Patient Speaker/Patient Perspective	Jasan Zimmerman
2:10 PM-2:25 PM	BREAK	



2:25 PM-2:50 PM	Case Study on Developing an Inhalational Therapy for Non-Cystic Fibrosis Bronchiectasis Part I: Patient Selection and Trial Duration Part II: Endpoint Considerations	Peter Kim, MD, FDA CDR LaRee Tracy, PhD, FDA
2:50 PM-4:20 PM	Moderated Panel Discussion (with Audience Q&A)	All Panelists
4:20 PM-4:30 PM	Closing Remarks	

Panelists:

External: Timothy Aksamit, Jeff Alder, Alan Barker, James Chalmers, Rajiv Dhand, Susan Ellenberg, Patrick Flume, Dean Follmann, Juergen Froehlich, Nicole Hamblett, Chip Hawkins, David Nichols, Peadar Noone, Anne O’Donnell, Greg Tino, Donald VanDeVanter, Pamela Zeitlin, Jasan Zimmerman

FDA: Maria Allende, Wen-Hung Chen, Ed Cox, Chris Kadoorie, Peter Kim, Deepika Lakhani, Robert Lim, Shrimant Mishra, Sumathi Nambiar, Quynh Nguyen, Thomas Smith, LaRee Tracy

Speaker slides and other workshop material can be found at:
<http://www.fda.gov/Drugs/NewsEvents/ucm602331.htm>
Public Internet Access:
Network: FDA-PUBLIC
Password: publicaccess