AGENDA

FDA Public Workshop

Development of Antibacterial Drugs for Treatment of Nontuberculous Mycobacterial Disease

April 8, 2019

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

Time	***Topic***	***Speaker(s) and Affiliation***
7:30 AM-8:30 AM	Registration	
8:30 AM-8:45 AM	Introductory Remarks and Panel Introduction	Ed Cox, FDA
Session 1: General Considerations for NTM Disease **Session Co-Chairs:** Sumathi Nambiar (FDA), James Chalmers (University of Dundee)		
8:45 AM-9:10 AM	Diagnosis and Treatment of NTM: Current State and Future Considerations	Anne O'Donnell, Georgetown University
9:10 AM-9:25 AM	Development of Antibacterial Drugs for NTM: A Regulatory Perspective	Peter Kim, FDA
9:25 AM-9:40 AM	Patient Perspective for Treatment of NTM Disease	Amy Leitman, NTM Info and Research
9:40 AM-9:55 AM	*BREAK*	
Session 2: Trial Design Considerations and Challenges for NTM Disease **Session Co-Chairs:** Sumathi Nambiar (FDA), James Chalmers (University of Dundee)		
9:55 AM-10:20 AM	Lessons Learned from Completed NTM Trials and Implications for Future Trials	Eugene Sullivan, Insmed
10:20 AM-10:45 AM	Trial Design Considerations and Examples	Kevin Winthrop, Oregon Health and Science University

10:45 AM-11:00 AM	Use of Patient-Reported Outcome Measures in NTM Trials	Wen-Hung Chen, FDA
11:00 AM-12:00 PM	Panel Discussion	All Panelists
12:00 PM-1:00 PM	**LUNCH**	
1:00 PM-1:30 PM	**Formal Public Comments** • Gyanu Lamichhane, Johns Hopkins University • Ho Namkoong, NIH • Khalid Dousa, Case Western Reserve University	
Session 3: Case Studies **Session Co-Chairs:** Karen Higgins (FDA), Patrick Flume (University of South Carolina)		
1:30 PM-1:40 PM	Presentation of Hypothetical Case Study #1: Development of a Novel Drug as an Add-on to a Background Regimen for Treatment of Pulmonary MAC Disease	Hiwot Hiruy, FDA
1:40 PM-2:05 PM	Academic and Industry Perspectives on Case Study #1	Academic: James Chalmers (University of Dundee) Industry: Angela Talley (Spero Therapeutics)
2:05 PM-3:00 PM	Moderated Panel Discussion (Case Study #1)	All Panelists
3:00-3:15 PM	*BREAK*	
3:15 PM-3:25 PM	Presentation of Hypothetical Case Study #2: Development of a New Drug Regimen for Treatment of Pulmonary MAC Disease	Hiwot Hiruy, FDA
3:25 PM-3:50 PM	Academic and Industry Perspectives on Case Study #2	Academic: Charles Daley (National Jewish Health) Industry: Ira Kalfus (RedHill Bio)

3:50 PM-4:45 PM	Moderated Panel Discussion (Case Study #2)	All Panelists
4:45 PM-5:00 PM	Summary	TBD
5:00 PM-5:15 PM	Closing Remarks	Ed Cox, FDA

All Panelists:

External: Timothy Aksamit (Mayo Clinic), Erica Brittain (NIH/NIAID), James Chalmers (University of Dundee), Charles Daley (National Jewish Health), Sonya Eremenco (Critical Path Institute), Patrick Flume (University of South Carolina), David Griffith (UT Health East Texas), Ira Kalfus (RedHill Bio), Shannon Kasperbauer (National Jewish Health), Amy Leitman (NTM Info and Research), Anne O'Donnell (Georgetown University), Kenneth Olivier (NIH/NHLBI), Mike Proschan (NIH/NIAID), Ashley Slagle (Aspen Consulting), Eugene Sullivan (Insmed), Angela Talley (Spero Therapeutics), Bruce Trapnell (University of Cincinnati/Savara Pharmaceuticals), Kevin Winthrop (Oregon Health Science University)

FDA: Wen-Hung Chen, Ed Cox, Cheryl Dixon, Karen Higgins, Hiwot Hiruy, Peter Kim, Robert Lim, Sumathi Nambiar

Speaker slides and other workshop material can be found at:
https://www.fda.gov/Drugs/NewsEvents/ucm629494.htm

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