AGENDA

FDA Virtual Public Workshop

Addressing Challenges in Inhaled Antifungal Drug Development

September 25, 2020

Time	Topic	Speaker(s) and Affiliation
9:00-9:10 AM	Introductory Remarks	John Farley, FDA
Session 1: Background and Nonclinical Considerations **Session Co-Chairs:** David Andes (University of Wisconsin-Madison), Shampa Das (University of Liverpool)		
9:10 AM-9:30 AM	What Place for Inhaled Antifungals in Pulmonary Medicine?	Richard Moss, Stanford University
9:30 AM-9:45 AM	Pharmacology and Toxicology Considerations for Inhaled Antifungals	Owen McMaster, FDA
9:45 AM-10:00 AM	Orally Inhaled Antifungal Drug Development: Clinical Pharmacology Perspective	Timothy Bensman, FDA
10:00 AM-10:30 AM	Regulatory Perspective for Device Development for Inhalation Combination Products Human Factors Considerations for Inhaled Antifungal Drug Development	Brandon Blakely, FDA Irene Chan, FDA
10:30 AM-10:40 AM	***BREAK***	
10:40 AM-10:55 AM	Considerations for Clinical Outcome Assessment Development	Christopher St. Clair, FDA
10:55 AM-11:05 AM	Patient Perspective (Video Comment)	Malcolm Birrell
11:05 AM-11:10 AM	Formal Public Comment	

	Sargramostim in the Management of Fungal Infections	Edwin Rock, MD, PhD Chief Medical Officer Partner Therapeutics
11:10 AM-12:00 PM	**LUNCH**	
Session 2: Clinical Trial Design Considerations for Inhaled Antifungal Development **Session Co-Chairs:** David Denning (University of Manchester), Kieren Marr (Johns Hopkins University School of Medicine)		
12:00 PM-12:20 PM	Regulatory Perspective for Inhaled Antifungal Products EMA Perspective for Inhaled Antifungal Drugs	Thomas Smith, FDA Radu Botgros, EMA
12:20 PM-1:00 PM	Allergic Bronchopulmonary Aspergillosis and the Role of Antifungals Endpoints Used for Studies of Antifungal Therapy in ABPA/Asthma	Rohit Bazaz, University of Manchester David Denning, University of Manchester
1:00 PM-1:40 PM	Overview of the Role of Inhaled Antifungals in Invasive Fungal Infections Antifungal Prophylaxis and Treatment in Solid Organ Transplant: Potential End Points of Inhaled Antifungal Administration	Kieren Marr, Johns Hopkins University School of Medicine Shahid Husain, University of Toronto
1:40 PM-1:50 PM	***BREAK***	
1:50 PM-2:30 PM	Perspectives and Lessons Learned from Industry: <u>Invasive Pulmonary Aspergillosis:</u> A Novel Inhaled Azole for IPA: Clinical and Regulatory Opportunities and Challenges	Lance Berman, Pulmocide

	Voriconazole Inhalation Powder for the Treatment of IPA – Defining the Key Attributes to Facilitate Approval <u>ABPA:</u> Perspectives on Inhaled Anti-Fungal Drug Development in ABPA Clinical Development of Therapeutics for ABPA: Experiences from a Clinical Study and Lessons Learned	Dale Christensen, TFF Pharmaceuticals Charlotte Keywood, Zambon Russell Clayton, Pulmatrix, Inc
2:30 PM-2:40 PM	***BREAK***	
2:40 PM-3:55 PM	**Moderated Panel Discussion** Moderators: David Denning (University of Manchester), Kieren Marr (Johns Hopkins University School of Medicine), Tom Walsh (Weill Cornell Medicine of Cornell University and New York Presbyterian Hospital) 1. As development of inhaled antifungal therapies will likely be based on streamlined development programs, what are the gaps in the animal/in vitro models that can be used to support these programs and how can they be addressed? 2. Discuss the appropriate endpoints, timing of assessment/length of studies and populations for clinical studies of inhaled antifungal agents in ABPA.	All Panelists (Listed Below)

	3. Discuss the appropriate endpoints and populations for clinical studies of inhaled antifungal drugs. Specifically discuss endpoints as they relate to the following: a. Treatment of invasive fungal infections. b. Prophylaxis of invasive fungal infections 4. For ABPA and IFI, discuss how we can advance/facilitate the efforts to develop patient reported outcome measures?	
3:55 PM-4:15 PM	Summary and Closing Remarks	Sumati Nambiar, FDA

All Panelists:

External:
Barbara Alexander (Duke University), David Andes (University of Wisconsin-Madison), Darius Armstrong-James (Imperial College London), Rohit Bazaz (University of Manchester, UK), Lance Berman (Pulmocide, Inc), Radu Botgros (European Medicines Agency), Dale Christensen (TFF Pharmaceuticals), Cornelius Clancy (University of Pittsburg), Russell Clayton (Pulmatrix, Inc), David Corry (Baylor College of Medicine), Shampa Das (University of Liverpool), David Denning (University of Manchester), Anthony Durmowicz (Cystic Fibrosis Foundation), Paul Greenberger (Northwestern University Feinberg School of Medicine), Shahid Husain (University of Toronto), Charlotte Keywood (Zambon), Kieren Marr (Johns Hopkins), Richard Moss (Stanford University), Luis Ostrosky-Zeichner (University of Texas Health Science Center at Houston), John Perfect (Duke University), Donald Sheppard (McGill University), William Steinbach (Duke University School of Medicine), David Stevens (Stanford University), Thomas Walsh (Weill Cornell Medicine of Cornell University and New York Presbyterian Hospital), Peter Wark (John Hunter Hospital, Australia)

FDA: Shukal Bala, Timothy Bensman, Brandon Blakely, Irene Chan, Phil Colangelo, Cheryl Dixon, John Farley, Caroline Jjingo, Yongman Kim, Robert Lim, Owen McMaster, Sumati Nambiar, Mark Needles, Khalid Puthawala, Thomas Smith, Christopher St. Clair

All speaker slides and other workshop materials can be found here after the meeting (please check for regular updates): https://www.fda.gov/drugs/news-events-human-drugs/addressing-challenges-inhaled-antifungal-drug-development-09252020-09252020

Adobe Connect Virtual Meeting Link:
https://collaboration.fda.gov/antifungaldrugs092520/