AGENDA

FDA Public Workshop

Development Considerations of Antifungal Drugs to Address Unmet Medical Need

August 4, 2020

VIRTUAL PUBLIC MEETING

Time	Topic	Speaker(s) and Affiliation
9:00 AM-9:10 AM EST	Introductory Remarks	John Farley, FDA
Session 1: Background, Pre-Clinical and Clinical Considerations **Session Co-Chairs: Sumati Nambiar, Erin Zeituni**		
9:10 AM-9:30 AM	Regulatory Considerations for Antifungal Drug Development EU Regulatory Considerations for Development of Antifungal Medicines	Sumati Nambiar, FDA Shohko Sekine, PMDA Radu Botgros, EMA
9:30 AM-9:45 AM	NIH Preclinical Services for Antifungal Product Development	Erin Zeituni, NIH
9:45 AM-10:05 AM	Animal Models of Fungal Infection	Thomas Walsh, Weill Cornell Medicine of Cornell University
10:05 AM-10:35 AM	Clinical Pharmacology Considerations for Antifungal Drug Development	Jason Moore, FDA William Hope, University of Liverpool
10:35 AM-10:45 AM	***BREAK***	
Session 2: Current State of Mold Infections and Antifungal Drug Development Considerations **Session Co-Chairs: Laura Kovanda, Yuliya Yasinskaya**		

10:45 AM-11:05 AM	Current State of Invasive Fungal Infections: Available Therapies and Unmet Need	Kieran Marr, Johns Hopkins
11:05 AM-11:35 AM	Lessons Learned from Development of Cresemba Antifungal Drugs to Address Unmet Medical Need: Olorofim	Laura Kovanda, Astellas John Rex, F2G
11:35 AM-11:45 AM	Patient Perspective	Matthew Schueler, Patient Representative
11:45 AM-11:55 PM	***BREAK***	
11:55 AM-12:35 PM	Design and Conduct of Clinical Trials for Newer Antifungal Agents Statistical Considerations	Peter Pappas, University of Alabama Cheryl Dixon, FDA Aaron Dane, DaneStat Consulting
12:35 PM-12:55 PM	Pediatric Antifungal Development Considerations	Aspasia Katragkou, New York Presbyterian, Methodist Hospital
12:55 PM-1:35 PM	***LUNCH***	
Session 3: Current State of Candida auris and Antifungal Drug Development Considerations **Session Co-Chairs: Helen Boucher, Louis Ostrosky-Zeichner**		
1:35 PM-1:50 PM	Overview of *Candida auris* and Emerging Resistant Candida	Tom Chiller, CDC
1:50 PM-2:05 PM	NIAID *Candida auris* Workshop Highlights and Funding Opportunities on Clinical Research	Baoying Liu, NIH

2:05 PM-2:35 PM	Developing New Antifungals for High Unmet Medical Needs: Lessons Learned and Development Considerations	Michael Hodges (Amplyx) David Angulo (Scynexis) Taylor Sandison (Cidara)
2:35 PM-2:55 PM	Clinical Trial Design Considerations	Luis Ostrosky-Zeichner, University of Texas Health Science Center
2:55 PM-3:05 PM	***BREAK***	
3:05 PM-4:45 PM	**Moderated Panel Discussion** Moderators: Helen Boucher and Louis Ostrosky-Zeichner 1. Discuss important factors to consider with regard to trial population, such as host factors, length/type of immunosuppression and any predisposing conditions (including COVID). Does the heterogeneity in trial population raise concerns? 2. What are the settings in which external controls and other alternative trial designs be used to obtain adequate and interpretable data? Are there gaps in the sources of external control data available and how can the needs be addressed? 3. What are some novel approaches and strategies to facilitate the development of antifungal drugs for children? 4. Discuss if consideration should be given to pooling different types of fungal infections or whether there are enough differences between the	All Panelists (Listed Below)

	species to warrant separate studies. Also discuss if there are important considerations with the body site of fungal infection as seen with antibacterial drugs. 5. What is the role for supportive preclinical animal model data to provide proof of concept that an investigational antifungal agent is active against an uncommon fungal disease (e.g., infections caused by Scedosporium, Lomentospora, Fusarium)? 6. Discuss how clinical trial networks can facilitate antifungal drug development and some of the barriers to establishing such networks.	
4:45 PM-5:00 PM	Summary and Closing Remarks	Yuliya Yasinskaya, FDA

All Panelists:

External: David Angulo (Scynexis), John Bennett (NIH), Radu Botgros (European Medicines Agency), Helen Boucher (Tufts Medical Center), Tom Chiller (CDC), Aaron Dane (DaneStat Consulting), David Denning (University of Manchester), Dennis Dixon (NIH), Michael Hodges (Amplyx), William Hope (University of Liverpool), Aspasia Katragkou (New York Presbyterian, Methodist Hospital), Laura Kovanda (Astellas), Baoying Liu (NIH), Shawn Lockhart (CDC), Johan Maertens (Ku Leuven, Belgium), Kieren Marr (Johns Hopkins School of Medicine), Luis Ostrosky-Zeichner (University of Texas Health Science Center), Peter Pappas (University of Alabama), Thomas Patterson (University of Texas Health Science Center), John Perfect (Duke University), John Rex (F2G), Taylor Sandison (Cidara), Matthew Schueler (Patient Representative), George Thompson (University of California-Davis), Thomas Walsh (Weill Cornell Medicine of Cornell University), Erin Zeituni (NIH), Lanling Zou (NIH)

FDA: Philip Colangelo, Cheryl Dixon, John Farley, Karen Higgins, Caroline Jjingo, Jason Moore, Sumati Nambiar, Elizabeth O'Shaughnessy, Yuliya Yasinskaya

Speaker slides, panelist affiliations/disclosures and other workshop materials can be found here (check for regular updates): https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/development-considerations-antifungal-drugs-address-unmet-medical-need-08042020-08042020

Virtual Adobe Meeting Link:
https://collaboration.fda.gov/antifungaldrugs080420/