AGENDA

FDA Public Workshop

Coccidioidomycosis (Valley Fever): Considerations for Development of Antifungal Drugs

August 5, 2020

VIRTUAL PUBLIC MEETING

Purpose of the Workshop: The purpose of this workshop is to hold scientific discussions to better understand the current state of coccidioidomycosis and potential strategies to facilitate the development of drugs that can be safely and effectively used to treat coccidioidomycosis. This workshop will bring together subject matter experts in the field of infectious diseases (ID), particularly fungal infections and coccidioidomycosis from academia, industry and other government agencies.		
Time	**Topic**	**Speaker(s) and Affiliation**
11:00 AM-11:15 AM (EST)	Introductory Remarks	John Farley, FDA
Session 1: Epidemiology, Clinical Manifestations and Development Resources **Session Co-Chairs: Susan Hoover, Lanling Zou**		
11:15 AM-11:35 AM	Coccidioidomycosis: Epidemiology/Clinical Manifestations as Relates to Trial Endpoints/Latin America	David Stevens, Stanford University
11:35 AM-11:55 AM	NIAID's Current Development Efforts and Resources for Product Development Targeting Valley Fever	Erin Zeituni, NIH
11:55 PM-12:10 PM	Animal Models of Coccidioidomycosis	Lisa Shubitz, University of Arizona
12:10 PM-12:20 PM	***BREAK***	
12:20 PM-12:35 PM	Patient Centered Clinical Trial Design	Rob Purdie, Valley Fever Institute

12:35 PM-12:50 PM	**Formal Public Comments** 1. Klaus Romero, Critical Path Institute *Topic: The relevance of FDA's and NCATS' CURE ID app as a tool to collect actionable RWD to identify signals and generate hypotheses to inform the design of trials for drug candidates against Valley Fever* 2. Gray Heppner, Crozet Biopharma *Topic: Vaccine development for coccidioidomycosis*	
12:50 PM-1:35 PM	**LUNCH**	
Session 2: Clinical Trial Considerations for Coccidioidomycosis Treatment **Session Co-Chairs: John Galgiani, Janis Blair**		
1:35 PM-1:55 PM	Clinical Trial Design Considerations for Coccidioidomycosis Drug Development	Elizabeth O'Shaughnessy, FDA
1:55 PM-2:15 PM	Investigator-Initiated Development of Nikkomycin Z. The Lesson Learned	John Galgiani, University of Arizona
2:15 PM-2:45 PM	Overview of Clinical Trials for Coccidioidomycosis Drug Development Data Driven Clinical Trial Design	Antonino Catanzaro, University of California San Diego Royce Johnson, Valley Fever Institute/Kern Medical
2:45 PM-2:55 PM	***BREAK***	
2:55 PM-3:30 PM	Comments from Industry	John Rex (F2G), Ed Garvey (Mycovia), David Angulo (Scynexis), Gareth Lewis (Mayne Pharma), David Larwood (Valley Fever Solutions)
3:30 PM-3:50 PM	Treatment Studies for Coccidioidomycosis: Past, Present and Future	Neil Ampel, University of Arizona

3:50 PM-4:00 PM	***BREAK***	
4:00 PM-5:20 PM	**Moderated Panel Discussion** Moderators: John Galgiani and Janis Blair 1. What are some considerations for drug development in specific populations (e.g., immunocompromised, pregnancy, pediatric patients)? 2. What are the key gaps in our knowledge to facilitate the development of drugs for the treatment of coccidioidomycosis and what are some suggestions to address them? 3. What is the appropriate use of biomarkers as endpoints in clinical trials of coccidioidomycosis?	All Panelists (Listed Below)
5:20 PM-5:30 PM	Summary and Closing Remarks	Sumati Nambiar, FDA

All Panelists:

External:
Neil Ampel (University. Arizona College of Medicine), David Angulo (Scynexis), Bridget Barker (Northern Arizona University), John Bennett (NIH), Janis E. Blair (Mayo Clinic), Antonino Catanzaro (University of California San Diego), Tom Chiller (CDC), Dennis Dixon (NIH), Erica Easton (Kern Medical Foundation), David Engelthaler (Tgen North, Phoenix, Arizona), John Galgiani (University of Arizona College of Medicine), Ed Garvey (Mycovia), Susan Hoover (Sanford Health), William Hope (University of Liverpool), Royce Johnson (Valley Fever Institute), Laura Kovanda (Astellas), David Larwood (Valley Fever Solutions), Gareth Lewis (Mayne Pharma), Baoying Liu (NIH), Shawn Lockhart (CDC), Hanna Oltean (Washington State Department of Health), Luis Ostrosky-Zeichner (University of Texas Health McGovern Medical School), Peter Pappas (University of Alabama), Thomas Patterson (University of Texas Health Science Center), Rob Purdie (Valley Fever Institute), John Rex (F2G, Ltd), Lisa Shubitz (University of Arizona), David Stevens (Stanford University), George Thompson (University of California—Davis), Carmelle Norice-Tra (NIH), Thomas Walsh (Cornell University), Nathan Wiederhold (University of Texas-San Antonio), Erin Zeituni (NIH), Lanling Zou (NIH)

FDA: Cheryl Dixon, John Farley, Karen Higgins, Sumathi Nambiar, Elizabeth O'Shaughnessy, Caroline Jjingo, Jason Moore, Elektra Papadopoulos, Julie Tierney

Speaker slides and other workshop materials can be found here (please check for regular updates): https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/developing-antifungal-drugs-treatment-coccidioidomycosis-valley-fever-infection-08052020-08052020

Adobe Connect Link:
https://collaboration.fda.gov/antifungaldrugs080520/