AGENDA

Public Workshop

Current State and Further Development of Animal Models of Serious Infections Caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa*

March 1, 2017

DoubleTree by Hilton Hotel Washington DC-Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910 (Pinnacle Grand Ballroom–2nd floor)

ABSTRACT: There are investigational therapies for bacterial diseases that are active against only a single species of bacteria and the target species is an infrequent cause of human disease. Given the narrow spectrum of activity of these therapies and the use of pre-study and concomitant therapy likely to be utilized when studying such a narrow spectrum drug, performing clinical trials of such drugs will likely be particularly challenging. These challenges were discussed at the July 18-19, 2016 FDA Public Workshop "Facilitating Antibacterial Drug Development for Patients with Unmet Need and Developing Antibacterial Drugs that Target a Single Species"[1]. While every effort should be made to perform such trials, animal models of serious bacterial infection may be useful to explore the activity of a candidate antibacterial drug targeting a single species and may help to predict whether the drug will be efficacious in humans.

This workshop will include an overview of the challenges with development of a new antibacterial drug targeting a single species, lessons learned from past and current animal models of infection development efforts, and discussion of next steps and research priorities.

Time	***Topic***	***Speaker(s) and Affiliation***
7:30-8:30 AM	Registration	
Clinical and Scientific Challenges		
8:30-8:50 AM	Introductory Remarks and Panel Introduction	Sumathi Nambiar, MD, MPH, FDA
8:50-9:05 AM	A Clinician's Perspective	Helen Boucher, MD, Tufts Medical Center

[1] Meeting materials including recordings and presentations available at: http://www.fda.gov/Drugs/NewsEvents/ucm497650.htm

9:05-9:45 AM	Challenges with Clinical Trial Design for a Drug Targeting a Single Species of Bacteria	John Rex, MD, CARB-X, F2G Ltd. Andreas Wallnofer, PhD, Polyphor Robin Isaacs, MD, Entasis Therapeutics
Lessons Learned and Considerations for Animal Model Development		
9:45-10:50 AM	Lessons Learned from the Development of Animal Models of Inhalational Anthrax, Pneumonic Plague, and Tularemia Approaches and Important Considerations in Animal Model Development for Bacterial Infections	Judith Hewitt, PhD, NIAID Gabriel Meister, PhD, Battelle Biomedical Research Center Julie Hutt, DVM, PhD, Lovelace Respiratory Research Institute Ed Cox, MD, MPH, FDA
10:50-11:10 AM	**BREAK**	
Pathogenesis ***Session Co-Chairs:*** *Samuel Miller, MD and Robert Bonomo, MD*		
11:10-11:25 AM	Pathogenesis of Pseudomonas	Joanna Goldberg, PhD, Emory University
11:25-11:40 AM	Pathogenesis of Acinetobacter	Robert Bonomo, MD, Case Western Reserve University
11:40-11:55 AM	Public Presentations	
11:55-12:25 PM	Moderated Panel Discussion (with Audience Q&A)	
12:25-1:25 PM	**LUNCH**	
Approaches to Animal Model Development, Future Direction/Next Steps ***Session Co-Chairs:*** *Sumathi Nambiar, MD, MPH and Jane Knisely, PhD*		

1:25-1:45 PM	PK/PD Considerations for Animal Model Development	David Andes, MD, University of Wisconsin
1:45-2:05 PM	Mouse Model of Pseudomonas Infection	Matthew Lawrenz, PhD, University of Louisville
2:05-2:25 PM	Mouse and Pig Models of Acinetobacter Infection	Daniel Zurawski, PhD, Walter Reed Army Institute of Research
2:25-2:45 PM	Rabbit Model of Pseudomonas Pneumonia	Binh Diep, PhD, University of California San Francisco
2:45-3:05 PM	Ventilated Pig Models of Pseudomonas Pneumonia	Gianluigi Li Bassi, MD, PhD University of Barcelona
3:05-3:25 PM	**BREAK**	
3:25-3:45 PM	Research Support and Resources	David Boucher, PhD BARDA Tina Guina, PhD, NIH/NIAID Thushi Amini, PhD, FDA
3:45-4:45 PM	Moderated Panel Discussion (with Audience Q&A)	**Panel Members**: David Andes (University of Wisconsin), Robert Bonomo (Case Western University), David Boucher (BARDA), Helen Boucher (Tufts Medical Center), Ed Cox (FDA), Binh Diep (University of California San Francisco), John Farley (FDA), Joanna Goldberg (Emory University), Tina Guina (NIH/NIAID), Judith Hewitt (NIH/NIAID), Julie Hutt (Lovelace Respiratory Research Institute), Jane Knisely (NIH/NIAID), Robin Isaacs (Entasis Therapeutics), Matthew Lawrenz (University of Louisville), Gianluigi Li Bassi (University of Barcelona), Gabriel Meister (Battelle Biomedical Research Center), Samuel Miller (University of Washington), Sumathi Nambiar (FDA), John Rex, MD, (CARB-X, F2G Ltd.),

		Andreas Wallnofer (Polyphor), Daniel Zurawski (Walter Reed Army Institute of Research)
4:45-5:00 PM	Closing Remarks	

Speaker slides and other workshop material can be found at:

http://www.fda.gov/Drugs/NewsEvents/ucm534031.htm