AGENDA

FDA Public Workshop

Development of Non-Traditional Therapies for Bacterial Infections

Day 1: August 21, 2018

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

Time	***Topic***	***Speaker(s) and Affiliation***
8:00-9:00 AM	Registration	
9:00 AM-9:15 AM	Introductory Remarks and Panel Introduction	Ed Cox, FDA
Session 1: Overview and Development Considerations		
9:15 AM-9:45 AM	Overview of Non-Traditional Therapies	John Rex, F2G Ltd. Kevin Outterson, Carb-X
9:45 AM-9:55 AM	Clinician's Perspective	Helen Boucher, Tufts
9:55 AM-10:05 AM	Pharmacology-Toxicology Considerations	Owen McMaster, FDA
10:05 AM-10:15 AM	Clinical-Pharmacology Considerations	Xiaohui (Tracey) Wei, FDA
10:15 AM-10:25 AM	Microbiology Considerations	Kalavati Suvarna, FDA
10:25 AM-11:00 AM	Clarifying Questions/Discussion	All Panelists
11:00 AM-11:15 AM	**BREAK**	
Session 2: Monoclonal Antibody Development for a prophylaxis indication: Case Study 1 **Monoclonal antibodies are proteins that target specific antigens and are being developed for treatment and prevention of various diseases. This session will discuss a hypothetical case of a monoclonal antibody targeting *Staphylococcus aureus* for the prevention of ventilator-associated bacterial pneumonia.**		

Session Co-Chairs: Filip Dubovsky (MedImmune), Dmitri Iarikov (FDA)		
11:15 AM-11:25 AM	Presentation of Case Study 1	Mayurika Ghosh, FDA
11:25 AM-11:35 AM	FDA and Industry Perspectives (5 minutes each)	Industry: Merck (Mary Beth Dorr) FDA: Mayurika Ghosh
11:35 AM-12:25 PM	Moderated Panel Discussion (with Audience Q and A)	All Panelists
12:25 PM-12:35 PM	Summary	
12:35 PM-1:35 PM	**LUNCH**	

1:35 PM-2:15 PM: Public Comments

- Paul Grint, MD, AmpliPhi Biosciences

- Jeff Wager, MD, EnBiotix, Inc.

- Samareh Azeredo da Silveira Lajaunias, PhD, Combioxin

- Raphael J. Mannino, PhD, Matinas BioPharma, Inc.

- Elizabeth Leininger, PhD, Aridis Pharmaceuticals

Session 3: Effect on Microbiome/Effect on Development of Resistance: Case Studies 2 and 3

Selective pressure from the presence of systemically administered antibacterial drugs in the gut can impact the gut microbiome, facilitate overgrowth of *C. difficile* and colonization by drug-resistant bacteria. There is also interest in developing products that can reduce carriage of organisms of certain resistance phenotypes in the gut and thereby potentially reduce the risk of acquiring infection among others in the community. In this session, hypothetical cases using both approaches will be discussed.

Session Co-Chairs: Kevin Outterson (Carb-X), Sumati Nambiar (FDA)

2:15 PM-2:25 PM	Presentation of Case Study 2	Ramya Gopinath, FDA
2:25 PM-2:35 PM	FDA and Industry Perspectives (5 minutes each)	Industry: Synthetic Biologics (Michael Kaleko) FDA: Ramya Gopinath

2:35 PM-3:25 PM	Moderated Panel Discussion (with Audience Q&A)	All Panelists
3:25 PM-3:40 PM	**BREAK**	
3:40 PM-3:50 PM	Presentation of Case Study 3	John Rex, F2G Ltd.
3:50 PM-4:50 PM	Moderated Panel Discussion (with Audience Q and A)	All Panelists
4:50 PM-5:15 PM	Summary	

Day 2: August 22, 2018

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

Time	***Topic***	***Speaker(s) and Affiliation***
8:00 AM-9:00 AM	Registration	
Session 4: Lysin Product Development: Case Study 4 **Lysins are therapeutic proteins derived from bacteriophages with an ability to degrade bacterial peptidoglycan in a species-specific or genus-specific manner. These products have a direct effect upon pathogens and are proposed to be used as either monotherapy or as adjunctive therapy in combination with other antibacterial drugs.** Session Co-Chairs: William Hope (University of Liverpool); Daniel Rubin (FDA)		
9:00 AM-9:10 AM	Presentation of Case 4	Ed Weinstein, FDA
9:10 AM-9:20 AM	FDA and Industry Perspectives (5 minutes each)	Industry: ContraFect Corporation (Cara Cassino) FDA: Ed Weinstein
9:20 AM-10:20 AM	Moderated Panel Discussion (with Audience Q&A)	All Panelists

10:20 AM-10:40 AM	**BREAK**	
10:40 AM-11:30 AM	Summary of the workshop	Ed Cox; John Rex
11:30 AM-11:45 AM	Closing Remarks	

Panelists:

FDA:
Edward Cox, Mayurika Ghosh, Ramya Gopinath, Dmitri Iarikov, Daniel Rubin, Sumati Nambiar, Owen McMaster, Kalavati Suvarna, Xiaohui (Tracey) Wei, Edward Weinstein

External:
Paul Ambrose, Michael Bevilacqua, Todd Black, Helen Boucher, Edward Burd, Cara Cassino, Wayne Dankner, Filip Dubovsky, Mary Beth Dorr, Shampa Das, Ann Eakin, Scott Evans, William Hope, Michael Kaleko, Wes Kim, Joe Larsen, Elizabeth Leininger (Day 2), David Melnick, Kevin Outterson, Toni Perez, Peter Potgeiter, John Rex, Mary Shatzoff, Vu Truong (Day 1), Brian Tse

Speaker slides and other workshop material can be found at:

https://www.fda.gov/Drugs/NewsEvents/ucm606052.htm

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