AGENDA

Development Considerations of Antimicrobial Drugs for the Treatment of Uncomplicated Urinary Tract Infections (uUTI) – Virtual Public Workshop

June 3, 2022

Goals of the Workshop: The Food and Drug Administration is sponsoring a public workshop to discuss drug development considerations of antimicrobial drugs for the treatment of uUTI. This meeting will bring together a diverse array of subject matter experts to discuss the following:

- ***Current state of clinical care for uUTI***
- ***Nonclinical considerations and pathophysiology***
- ***Microbiological and clinical pharmacology tools and approaches***
- ***Trial design considerations***

Time	***Topic***	***Speaker(s) and Affiliation***
9:00 AM-9:10 AM	Introductory Remarks and Panel Introduction	Peter Kim, FDA
Session 1: Background **Session Co-Chairs: Timothy Bensman (FDA), Barbara Trautner (Baylor College of Medicine)**		
9:10 AM – 9:30 AM	Current State of Clinical Care for uUTI in the United States	Barbara Trautner, Baylor College of Medicine
9:30 AM – 9:50 AM	Virulence Studies and Properties of Bacterial Strains Causing uUTI	Harry Mobley, University of Michigan
9:50 AM – 10:00 AM	**BREAK**	

	Clinical Pharmacology Considerations	
10:00 AM – 10:20 AM	Current State of Antibacterial PK/PD in uUTI Animal Models	Tomefa Asempa, Hartford Healthcare
10:20 AM – 10:40 AM	The Role of Dynamic in vitro Simulations to Inform Treatment Decision in uUTIs	Jason Roberts (University of Queensland) and Iain Abbott (Monash University) (pre-recorded presentations)
10:40 AM – 11:00 AM	Pharmacokinetic-Pharmacodynamic Considerations in Drug Development Decision Making for Uncomplicated Urinary Tract Infection Indication	Keith Rodvold, University of Illinois Chicago
	Patient Perspectives	
11:00 AM – 11:10 AM	Patient Centered Considerations in Care: Lived Experience with uUTI	Janice Tufte, Patient Representative
11:10 AM – 11:20 AM	Patient Experience with uUTI	Valerie Price, Patient Representative (pre-recorded presentation)
	Formal Public Comment	
11:20 AM – 11:30 AM	Novel Oral Agents for Gram-Negatives: The Role of uUTI Studies	Cornelius Clancy, University of Pittsburgh (on behalf of IDSA)
11:30 AM – 12:20 PM	**LUNCH**	
Session 2: Trial Design Challenges and Considerations **Session Co-Chairs: Mukil Natarajan (FDA), Kalpana Gupta (Boston University)**		
12:20 PM – 12:40 PM	FDA Perspective on uUTI Trial Design	Mukil Natarajan, FDA
12:40 PM – 1:00 PM	Regulatory Perspective from the European Medicines Agency	Radu Botgros, EMA

1:00 PM – 1:15 PM	Discordance of Clinical and Microbiological Endpoints in Clinical Trials for Complicated Urinary Tract Infections (cUTI)	Nadia Kadry, FDA
1:15 PM – 1:35 PM	Investigator's Perspective	Ann Stapleton, Eisenhower Health
	Developer's Perspectives	
1:35 PM – 1:45 PM	Developer's Perspectives on Inclusion Criteria and Endpoints for uUTI Clinical Trials	Tom Hadley, Utility Therapeutics
1:45 PM – 1:55 PM	Developer's Perspective on the Primary Endpoint in uUTI Trials and Lessons Learned	Sailaja Puttagunta, Iterum Therapeutics
1:55 PM – 2:05 PM	Developer's Perspective on Urinary Breakpoints for uUTI	Nicole Scangarella-Oman, GSK
2:05 PM – 2:15 PM	**BREAK**	
2:15 PM – 3:35 PM	**Moderated Panel Discussion** **Panel Moderators: Peter Kim (FDA) and Thomas Hooton (University of Miami)** <u>Questions to Panel:</u> 1. Please discuss the pros and cons of the currently recommended composite (clinical + microbiological) primary endpoint for uUTI studies. (*35 minutes*) 2. Please discuss what would be acceptable active comparators in uUTI non-inferiority studies. (*20 minutes*)	All FDA and External Panelists to Participate (Panelists listed on Page 4)

	3. Please discuss the pros and cons regarding the use of urine-specific breakpoints for the development of antibacterial drugs for uUTI. Please also comment on what studies would be helpful to evaluate urine-specific breakpoints. (*25 minutes*)	
3:35 PM – 3:45 PM	Summary and Closing Remarks	Peter Kim, FDA

All Panelists:

FDA:

Timothy Bensman, Zhixia (Grace) Yan Danielsen, Kerian Grande Roche, Hiwot Hiruy, Dmitri Iarikov, Nadia Kadry, Peter Kim, Xianbin Li, Cristina Miglis, Mukil Natarajan, Daniel Rubin, Jalal Sheikh

External (see full panelist Affiliations and Disclosures using the workshop webpage link below):

Iain Abbott, Monash University (Australia); Tomefa Asempa, Hartford Healthcare; Radu Botgros, European Medicines Agency; Erica Brittain, NIAID; Dmitri Drekonja, University of Minnesota; Scott Evans, George Washington University; Kalpana Gupta, Boston University; Tom Hadley, Utility Therapeutics; Thomas Hooton, University of Miami; Salim Janmohamed, GSK; Harry Mobley, University of Michigan; Keith Rodvold, University of Illinois Chicago; Jason Roberts, University of Queensland (Australia); Valerie Price, Patient Representative; Sailaja Puttagunta, Iterum Therapeutics; Nicole Scangarella-Oman, GSK; Ann Stapleton, Eisenhower Health; Barbara Trautner, Baylor College of Medicine; Janice Tufte, Patient Representative

Speaker slides and other workshop materials will be posted before/after workshop at:

Workshop Webpage Link (with registration): https://www.fda.gov/drugs/news-events-human-drugs/development-considerations-antimicrobial-drugs-treatment-uncomplicated-urinary-tract-infections-uti

Public Zoom Link (day of meeting): https://fda.zoomgov.com/j/1616027961?pwd=MlpvRHJmK0pjRWlEZzd4VUtoMGFyQT09

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