**AGENDA**

**Drug Development Considerations for Empiric Antibacterial Therapy in Febrile Neutropenic Patients—Virtual Public Workshop**

**April 23, 2024**

**Goals of the workshop: The Food and Drug Administration is sponsoring a public workshop to discuss drug development considerations of empiric therapy in febrile neutropenic patients. This meeting will bring together a diverse array of subject matter experts to discuss the following:**

- Current state of development and the need for antibacterial drugs for empiric therapy in febrile neutropenic patients
- Design and operational challenges of clinical trials in febrile neutropenia

| Time | Topic | Speaker(s) and Affiliation |
|---|---|---|
| 9:00 AM-9:10 AM | Introductory Remarks | Peter Kim, FDA |
| ***Session 1. Background (Session Moderators: Andrea Zimmer and Robert Pease)*** | | |
| 9:10 AM-9:25 AM | Historical perspective on prophylaxis and empiric therapy of febrile neutropenia | Randy Taplitz, City of Hope National Medical Center |
| 9:25 AM-9:35 AM | Current options for empiric treatment of febrile neutropenia | Andrea Zimmer, University of Nebraska Medical College |
| 9:35 AM-9:45 AM | Diagnostic testing in febrile neutropenia | Kimberly Hanson University of Utah |
| 9:45 AM-9:55 AM | Antibiotic management for neutropenic patients following a nuclear detonation incident | Anita Sheoran, BARDA |
| 9:55 AM-10:05 AM | Clinical development of antibiotics for empiric therapy of febrile neutropenia: industry perspective | Douglas Girgenti, Melinta Therapeutics |
| 10:05 AM-10:15 AM | **Break** | |
| ***Session 2. Regulatory Perspective and Trial Design Challenges and Considerations (Session Moderators: Radu Botgros and Daniel Rubin)*** | | |
| 10:15 AM-10:25 AM | Empiric antibacterial therapy in patients with febrile neutropenia: regulatory pathways and programs to expedite drug development | Robert Pease, FDA |
| 10:25 AM-10:45 AM | Regulatory perspective on clinical trial design considerations for empiric antibacterial therapy in febrile neutropenia | Rama Kapoor, FDA |
| 10:45 AM-11:00 AM | Statistical considerations in clinical trials in febrile neutropenia | Daniel Rubin, FDA |

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| 11:00 AM-<br>11:15 AM | European Medicines Agency and Pharmaceuticals and Medical Devices Agency perspectives | Radu Botgros, EMA<br>Katsuhiko Ichimaru, PMDA |
| 11:15 AM-<br>11:25 AM | **Break** | |
| 11:25 AM-<br>12:45 PM | ***Moderated Panel Discussion (Panel Moderators: Randy Taplitz and Dmitri Iarikov)***<br>1. Please discuss the greatest unmet needs for empiric treatment of febrile neutropenia.<br>• Please comment on an ideal drug profile.<br>2. Discuss strategies for enrichment of the study population in patients most likely to have a bacterial etiology for their fever (e.g., clinical characteristics, diagnostics, etc.).<br>3. Regarding trial design considerations in febrile neutropenia:<br>• Please discuss what would be an appropriate primary endpoint and when it should be assessed.<br>• Please discuss the primary efficacy population.<br>• Are there strategies to make trials more feasible?<br>4. We note that there are limited data on the use of new antibacterial drugs in neutropenic patients. If time allows and recognizing that this question is not directly related to empiric treatment of febrile neutropenia, please comment on the need, utility and feasibility of obtaining efficacy and safety data for new drugs in the treatment of neutropenic patients with defined systemic bacterial infections. | |
| 12:45 PM-<br>1:00 PM | Summary and Closing Remarks | Dmitri Iarikov, FDA |

## All Speakers and Panelists:

**FDA**: John Farley, Dmitri Iarikov, Rama Kapoor, Peter Kim, Robert Pease, Daniel Rubin, Adam Sherwat

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

**Radu Botgros**, European Medicines Agency (EMA); **Juan Gea-Banacloche**, National Institute of Allergy and Infectious Diseases (NIAID); **Alison Freifeld**, University of Nebraska Medical Center; **Douglas Girgenti**, Melinta Therapeutics; **Kimberly Hanson**, University of Utah; **Katsuhiko Ichimaru**, Pharmaceuticals and Medical Devices Agency (PMDA); **Gary Lyman**, Fred Hutchinson Cancer Center; **Catherine Liu**, Fred Hutchinson Cancer Center; **Kieren Marr**, Elion Therapeutics; **Michael Satlin**, Weill Cornell Medicine; **Anita Sheoran**, Biomedical Advanced Research and Development Authority (BARDA); **Lynne Strasfeld**, Oregon Health and Science University; **Randy Taplitz**, City of Hope National Medical Center; **Andrea Zimmer**, University of Nebraska Medical College

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

Workshop Webpage Link (with registration): https://www.fda.gov/drugs/drug-development-considerations-empiric-antibacterial-therapy-febrile-neutropenic-patients-04232024

Public Zoom Link (day of meeting): Register in advance for this webinar using this Zoom link. After registering, you will receive a confirmation email containing information about joining the webinar.