AGENDA

FDA-CDC-NIAID Virtual Public Workshop

Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea

April 23, 2021

Goals of the Workshop: FDA, CDC and NIAID are co-sponsoring a public workshop to discuss drug development considerations of antimicrobial drugs for the treatment of uncomplicated gonorrhea. This meeting will bring together a diverse array of subject matter experts and stakeholders from academia, industry, regulatory authorities and other government agencies to discuss potential strategies aimed to facilitate and accelerate development of new therapies. Topics will include:

- ***Areas of current and future needs, current challenges and ideas to address these challenges***
- ***Nonclinical models***
- ***Microbiological and clinical pharmacology tools and approaches***
- ***Trial design considerations, enrollment strategies, choice of comparators and trial population***

Time	***Topic***	***Speaker(s) and Affiliation***
9:00 AM-9:15 AM	Introductory Remarks	John Farley, FDA Laura Bachmann, CDC Carolyn Deal, NIAID
Session 1: Background and Pre-Clinical Considerations **Session Co-Chairs: Kyle Bernstein (CDC), Yuliya Yasinskaya (FDA)**		
9:15 AM-9:30 AM	**Gonorrhea Treatment Strategies: Needs and Emerging Data to Address Future Challenges**	Jeanne Marrazzo, University of Alabama

9:30 AM-9:45 AM	**Antibiotic Resistant Gonorrhea: Policy Considerations and Implications for Drug Development**	Teodora Wi, World Health Organization
9:45 AM-10:00 AM	**Treatment of Gonorrhea: Current State and Future Considerations**	Laura Bachmann, CDC
10:00 AM-10:30 AM	**Antimicrobial Resistance in *Neisseria gonorrhoeae* (NG) and Pharmacokinetic/Pharmacodynamic (PK/PD) Considerations**	Magnus Unemo, Orebro University George Drusano, University of Florida
10:30 AM-10:45 AM	**Animal Models for Pre-clinical Testing of Antibiotics Against Gonorrhea: Established and New Models Under Development**	Ann Jerse, Uniformed Services University
10:45 AM-10:55 AM	**BREAK**	
10:55 AM-11:10 AM	**Preclinical Efforts to Support Gonorrhea Drug Development**	Thomas Hiltke, NIAID
11:10 AM-11:25 AM	**Funding Efforts to Support Gonorrhea Drug Development**	Erin Duffy, CARB-X
11:25 AM-11:50 AM	**STI Clinic and Public Health Perspective**	Hilary Reno, Washington University Candice McNeil, Wake Forest University Health Sciences
11:50 AM-12:10 PM	**Formal Public Comment** Antibiotic-Resistant Gonorrhea Among Adolescents and Young Adults: Need for Early Education	Sarah Wang, University of California Irvine
12:10 PM-12:40 PM	**LUNCH**	

Session 2: Trial Design Challenges and Considerations **Session Co-Chairs: Carolyn Deal (NIAID), Peter Kim (FDA)**		
12:40 PM-1:25 PM	**Regulatory Perspectives on Development of Antibacterial Drugs for Gonorrhea**	Hiwot Hiruy, FDA Sumathi Nambiar, FDA (on behalf of Junko Sato, PMDA) Radu Botgros, EMA
1:25 PM-2:40 PM	**Overview of Drug Development Considerations for Uncomplicated Gonorrhea** **Developer Perspectives on Recent Challenges and Lessons Learned**	Sue Cammarata, Tunnell Government Services Ricardo Chaves, Debiopharm International Caroline Perry, GSK Seamus O'Brien, GARDP Steve Gelone, Nabriva Therapeutics
2:40 PM-3:10 PM	**Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea: Investigator Perspectives**	Edward Hook, University of Alabama-Birmingham
3:10 PM-3:20 PM	**BREAK**	
3:20 PM-4:40 PM	Moderated Panel Discussion (**Moderators: Edward Hook and Kimberly Workowski**) **<u>Panel Discussion Topics:</u>** **Q1:** Please discuss issues around trial enrollment as it pertains to the patient population	All Panelists (Listed Below)

	Q2: Please discuss considerations to facilitate trial conduct and suggestions to overcome challenges that have been presented **Q3:** Please discuss issues around trial design, considering the impact of revised treatment guidelines **Q4:** Please discuss considerations for optimizing dose and regimen selection **Q5:** Please comment on safety considerations for new antimicrobial products, such as the size of the safety database and collection of additional postmarketing safety data	
4:40 PM-5:00 PM	Summary and Closing Remarks	Sumathi Nambiar, FDA

All Panelists:

External: Lindley Barbee (University of Washington), Radu Botgros (EMA), Juan Bravo (Debiopharm International SA), Sue Cammarata (Tunnell Government Services), Ricardo Chaves (Debiopharm International SA), Guennaelle Dieppois (Debiopharm International SA), George Drusano (University of Florida), Erin Duffy (CARB-X), Scott Evans (George Washington University), Helen Fifer (Public Health England), Steve Gelone (Nabriva Therapeutics), Khalil Ghanem (Johns Hopkins University), Matthew Golden (University of Washington), Edward Hook (University of Alabama-Birmingham), Ann Jerse (Uniformed Services University), Jeff Klausner (USC), Jeanne Marrazzo (University of Alabama-Birmingham), Candice McNeil (Wake Forest University Health Sciences), Seamus O'Brien (GARDP), Caroline Perry (GlaxoSmithKline), Hilary Reno (Washington University), Nicole Scangarella-Oman (GlaxoSmithKline), Olusegun Soge (University of Washington), Magnus Unemo (Orebro University), Brian VanScoy (Institute for Clinical Pharmacodynamics), Teodora Elvira Wi (WHO), Kimberly Workowski (Emory University), Jonathan Zenilman (Johns Hopkins University)

FDA, NIAID, CDC Participants (Co-Sponsors): Laura Bachmann (CDC), Kyle Bernstein (CDC), Carolyn Deal (NIAID), Ann Eakin (NIAID), John Farley (FDA), Thomas Hiltke (NIAID), Hiwot Hiruy (FDA), Seong Jang (FDA), Peter Kim (FDA), Sumathi Nambiar (FDA), Lori Newman (NIAID), Kerian Grande Roche (FDA), Raul Romaguera (CDC), Dan Rubin (FDA), Yuliya Yasinskaya (FDA)

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

https://www.fda.gov/drugs/news-events-human-drugs/development-considerations-antimicrobial-drugs-treatment-gonorrhea-04232021-04232021

Adobe Connect Virtual Meeting Link: https://collaboration.fda.gov/cderond042321/