AGENDA

FDA Public Workshop

Development of New Tuberculosis Treatment Regimens-- Scientific and Clinical Trial Design Considerations

July 19, 2017

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

Time	***Topic***	***Speaker(s) and Affiliation***
7:30-8:30 AM	Registration	
8:30 AM-8:45 AM	Introductory Remarks and Panel Introduction	Ed Cox, MD, MPH, FDA
Landscape and Pre-clinical Approaches to Inform Clinical Candidates for TB Combination Regimens **Session Co-Chairs:** John Farley (FDA), Philip LoBue (CDC)		
8:45 AM-9:25 AM	Landscape and Important Challenges	Philip LoBue, MD, CDC Cathy Bansbach, PhD, Gates Foundation
9:25 AM-9:40 AM	Need and Accessibility of New TB Drug Regimens: Patient and Community Perspective	Erica Lessem, MPH, Treatment Action Group
9:40 AM-10:00 AM	What's New in Pre-Clinical Tools Used for Evaluation of New Components of TB Regimens	Eric Nuermberger, MD, Johns Hopkins
10:00 AM-10:20 AM	Assessing TB Drug Pharmacokinetics in Clinical Studies	Charles Peloquin, PharmD, University of Florida

10:20 AM-10:40 AM	TB Biomarkers and Clinical Utility	Payam Nahid, MD, MPH, UCSF
10:40 AM-10:55 AM	**BREAK**	
10:55 AM-11:15 AM	New Approaches to TB Diagnostics	Marco Schito, PhD, Critical Path Institute
11:15 AM-11:35 AM	CPTR Role in Facilitating TB Drug Development	Debra Hanna, PhD, Critical Path Institute
11:35 AM-11:55 AM	Formal Public Presentations	
11:55 AM-12:35 PM	Moderated Panel Discussion (with Audience Q&A)	All Panelists
12:35 PM-1:35 PM	**LUNCH**	

New Clinical Approaches to TB Regimen Development

Session Co-Chairs: Sumathi Nambiar (FDA), Mel Spigelman (TB Alliance)

1:35 PM-1:55 PM	Regulatory Overview	Karen Higgins, Sc.D., FDA
1:55 PM-2:35 PM	New Approaches to TB Drug Development: Developer and Industry Perspective	Mel Spigelman, MD, TB Alliance Charles Wells, MD, Sanofi
2:35 PM-2:55 PM	Tuberculosis Trials Consortium: CDC Experience	Andrew Vernon, MD, MHS, CDC
2:55 PM-3:15 PM	Trial Design Considerations in Pediatric Populations	Jeffrey Starke, MD, Baylor College of Medicine
3:15 PM-3:30 PM	**BREAK**	
3:30 PM-3:50 PM	Lessons Learned from Completed TB Trials and Implications for Future Trials	Christian Lienhardt, MD, PhD, WHO
3:50 PM-4:50 PM	Moderated Panel Discussion (with Audience Q&A)	All Panelists Confirmed Panelists (in addition to listed speakers): Lawrence Geiter

		(Otsuka), David Hughes (Novartis), Patrick Phillips (University of California San Francisco), Dakshina Chilukuri (FDA), John Farley (FDA), Steve Gitterman (FDA), Dmitri Iarikov (FDA), Sumathi Nambiar (FDA), Sheral Patel (FDA), Joe Toerner (FDA), Yuliya Yasinskaya (FDA)
4:50 PM-5:00 PM	Closing Remarks	

Speaker slides and other workshop material can be found at:

http://www.fda.gov/Drugs/NewsEvents/ucm548365.htm

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