23 November 2016
EMA/427839/2016

Final agenda - Workshop on update of TB Guideline

25 November 2016, 09.00-16.00 (UK time) European Medicines Agency, London, room 2A

Chair/Co-Chairs: M. Cavaleri/ F. Drobniewski

Item	Time	Agenda	Speakers	
1.	09:00	Welcome and Introductions	Chairs	10’
2.	09:10	Summary of the guideline and aims of the workshop	Mair Powell (MHRA, IDWP)	10’
		Topic 1: Selection of agents, doses and regimens for clinical study		
3.	09:20-09:50	In vitro models and animal models	Debra Hanna (CPTR)	30’
4.	09:50-10:05	Industry/Developers Perspective	David Barros-Aguirre (GSK)	15’
5.	10:05-10:20	Discussion		15’
		Topic 2: Efficacy endpoints in clinical trials		
6.	10:20-10:50	Endpoints that may correlate with cure Validation of biomarkers	Geraint Davies (University of Liverpool)	30’
	10:50-11:10	Coffee break		20’
7.	11:10-11:25	Industry/Developers Perspective	Lawrence Geiter (Otsuka)	15’
8.	11:25-11:40	Industry/Developers Perspective	Robert Wallis (Aurum Institute)	15’
9.	11:40-12.00	Discussion		20’

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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		Topic 3: Clinical development strategies and trial designs		
		Evaluation of new treatment regimens		
10.	12.00-13.00	Considerations on study design A clinician's perspective Microbiological aspects related to eligibility and outcome	Andrew Nunn (University College London)	20'
			Andreas Diacon (Stellenbosch University)	20'
			Stephen Gillespie (University of St. Andrews)	20'
	13.00-14:00	Lunch		60'
11.	14.00-14:40	Industry/developers perspective	Myriam Theeuwes (Janssen)	40'
			Carl Mendel (TB Alliance)	
12.	14:40-15.00	WHO perspective	Christian Lienhardt (WHO)	20'
12.	15.00-15:30	Discussion		30'
13.	15:30-16:00	Summary and closing remarks	Co-Chairs and Rapporteur	30'