EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2012
EMA/225314/2012
Human Medicines Development and Evaluation

Agenda – workshop on development of new antibacterial medicines

25 October 2012 - Meeting room 3A 13.00 – 18.00

26 October 2012 - Meeting room 3A 09.00 – 15.45

Co-Chairs: Prof. Eleni Giamarellou (Athens, Greece)
Dr. Marco Cavaleri (EMA)

Rapporteur: Dr Mair Powell (Chair - Infectious Diseases Working Party (IDWP))

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Thursday 25 October 2012, 13.00pm - 18.00pm

Item	Agenda	Name	Timing
	Welcome and housekeeping	Chairs and EMA	13:00-13:10
	Aims of the meeting	Radu Botgros (EMA)	13:10-13:15
1.	**Introduction**		
	TATFAR-the EU-US forum	Marco Cavaleri (EMA)	13:15-13:25
2.	**Drugs targeting multi-resistant (MDR) pathogens**		
	Regulatory Status	Mair Powell (IDWP)	13:25-13:35
	Pharmacokinetics-pharmacodynamics (PK/PD)		
Academia:	Bridging the bench to bedside divide: Optimal dosing regimens of novel antimicrobials against MDR pathogens	George Drusano (University of Florida, USA)	13:35-13:50
	Questions and answers		13:50-13:55
	Antibiotic development for resistant bacteria: A pharmacometric-based solution	Paul Ambrose (Institute for Clinical Pharmacodynamics, USA)	13:55-14:10
	Questions and answers		14:10-14:15
	Clinical trials		
Academia:	IDSA (Infectious Diseases Society of America) position	Helen Boucher (IDSA, USA)	14:15-14:30
	Treatment of serious infections due to MDR *Acinetobacter baumannii*. Presentation of a multicenter randomized clinical trial	Riccardo Utili (University of Naples, Italy)	14:30-14:40
	Questions and answer		14:40-14:45
Industry :	Drugs for MDR pathogens - Issues in development	Mark Goldberger (Abbott, USA)	14:45-15:00
	Example scenarios: outline proposals of possible development programmes for specific types of products:		
	Issues to address for a new active substance (NAS) with fairly broad spectrum that will include one or more multi-resistant/extended resistant (MDR/XDR) pathogens	Barry Eisenstein (Cubist, USA)	15:00-15:10
	Issues to address for a NAS with narrow/very narrow spectrum that will include one or more MDR/XDR pathogens	Aaron Dane (AstraZeneca, UK)	15:10 -15:20
	Considerations in the development of beta-lactamase inhibitor combination products for MDR pathogens	Mike Dudley (Rempex, USA)	15:20-15:30
	COFFEE BREAK		15:30-16.00
	Discussion		16:00-18:00

Friday 26 October 2012, 09.00am – 15.45pm

Item	Agenda	Name	Timing
	Outline of structure of the day	Radu Botgros (EMA)	09:00-09:10
3.	**Companion diagnostics for the rapid diagnosis of MDR pathogens**		
Academia:	Challenges to develop diagnostics for treatment of MDR pathogens	Herman Goossens (University of Antwerp, Belgium)	09:10 – 09:20
Industry:	Diagnostics - A focus on use in development of drugs for MDR pathogen	John Rex (AstraZeneca, UK)	09:20 – 09:30
	Discussion		09:30 – 09:50
4.	**Discussion on specific indications: Hospital acquired pneumonia/ Ventilator associated pneumonia (HAP/VAP)**		
	Regulatory status	Mair Powell (IDWP)	09:50 – 09:55
Academia:	Guidelines HAP/VAP. Standpoint from academics	Serge Kouzan (St Julien en Genevois Hospital, France)	09:55 – 10:05
Industry:	HAP-VAP	David Friedland (Forest-Cerexa, USA)	10:05 – 10:15
	Discussion		10:15 – 10:35
	COFFEE BREAK		10:35 – 11:05
5.	**Discussion on specific indications: Community acquired pneumonia (CAP) (PORT III and IV)**		
	Regulatory status	Mair Powell (IDWP)	11:05 – 11:10
Academia:	Clinical trials in CAP	Francesco Blasi (University of Milan, Italy)	11:10 – 11:20
Industry:	Community-acquired pneumonia (CAP)	Keith Barker (GSK, UK)	11:20 – 11:30
	Discussion		11:30 – 11:50
6.	**Discussion on specific indications: Urinary tract infections (UTI), intra-abdominal infections (IAI), skin and soft tissue infections (SSTI)**		
	Regulatory status	Mair Powell (IDWP)	11:50 - 11:55
	Discussion		11:55 – 12:15
	LUNCH		12:15 - 13:15
7.	**Discussion on specific indications: Bacteraemia**		
	Regulatory status	Mair Powell (IDWP)	13:15 – 13:20
Academia:	Bacteremia or severe sepsis as indication?	Bart Rijnders (Erasmus MC Hospital, Netherlands)	13:20 – 13:30
Industry:	Development of drugs for bacteraemia	Charles Knirsch (Pfizer, USA)	13:30 - 13:40
	Discussion		13:40 – 14:00

8. Eradication of carriage			
	Regulatory status	Mair Powell (IDWP)	14:00 – 14:05
Academia:	Presentation	Jan Kluytmans (Amphia Hospital, Netherlands)	14:05 - 14:15
Industry:	Development of drugs for eradication of nasal carriage of *S.aureus* to reduce *S.aureus* infections in vulnerable surgical patients	Richard Bax (Transcrip, UK)	14:15 – 14:25
	Discussion		14:25 - 14:45
9. Inhaled drugs for non- cystic fibrosis (CF) indication			
	Regulatory status	Mair Powell (IDWP)	14:45 – 14:50
Academia:	Inhaled antibiotics in non-CF bronchiectasis	Michael Loebinger (Imperial College London, UK)	14:50 – 15:00
Industry:	Inhalational antibacterial regimens in non cystic fibrosis patients	Jeff Alder (Bayer, USA)	15:00 - 15:10
	Discussion		15:10 - 15:30
SUMMARY OF MEETING AND NEXT STEPS		Mair Powell (IDWP)	15:30 - 15:45
	END OF MEETING		15:45

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