EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2015
EMA/400205/2015
European Medicines Agency

# Agenda - Pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products

12-13 November 2015, meeting room 2A

Co-Chairs: Marco Cavaleri, Alasdair McGowan

| Item | Time | Agenda | Speakers | |
|---|---|---|---|---|
| | | **Thursday 12 November 2015 – Day 1** | | |
| 1. | 13:00 | Welcome and Introductions | Co-Chairs: Marco Cavaleri, Alasdair McGowan | |
| 2. | 13:15 | Aims of the workshop | Rapporteur: Mair Powell | |
| | 13:30-14:50 | Topic 1: Nonclinical models to identify PK-PD indices and PD targets | | |
| 3. | | In vitro | George Drusano | 20’ |
| 4. | | In vivo | Sujata M. Bhavnani | 20’ |
| 5. | | Industry Perspective | Kevin Krause (Achaogen) | 20’ |
| 6. | | Discussion | | 20’ |
| | 14:50-15:20 | Coffee break | | |

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|---|---|---|---|---|
| | 15:20-16:50 | Topic 2: PK data for supporting PK-PD analyses | | |
| | | Essential PK data (volunteers vs. patients, sparse sampling considerations, protein binding) | Elisabet Nielsen | 30’ |
| | | ELF data (study design, interpretation, role in dose selection) | William Hope | 20’ |
| | | Industry Perspective | David Tenero (GSK) | 20’ |
| | | Discussion | | 20’ |
| | 16:50-18:00 | Topic 3: PD targets and PTA | | |
| | | PD targets for various infection types. Stasis vs. 1-log kill vs. 2-log kill | Paul Ambrose<br>George Drusano | 30’ (total) |
| | | Industry Perspective | Mike Dudley (The Medicines Company) | 20’ |
| | | Discussion | | 20’ |
| | 18:00 | Closing of day 1 | | |
| | | **Friday 13 November 2015 – Day 2** | | |
| | 09:00-10:10 | Topic 3 continued: PD targets and PTA | | |
| | | Estimating PTA | George Drusano | 15’ |
| | | | Johan Mouton | 15’ |
| | | Industry Perspective | Matthew Rizk (Merck) | 20’ |
| | | Discussion | | 20’ |
| | 10:10-11:20 | Topic 4: Clinical exposure-response relationships | | |
| | | Review of clinical trial data | Alasdair McGowan | 15’ |
| | | CER methods | Johan Mouton | 15’ |
| | | Industry Perspective | Evelyn J. Ellis-Grosse (Zavante Therapeutics) | 20’ |
| | | Discussion | | 20’ |
| | 11:20-11:40 | Coffee break | | |
| | 11:40-13:00 | Topic 5: Beta-lactamase inhibitors | | |
| | | Inhibitor properties. Microbiology and enzymology | David Livermore | 20’ |
| | | Issues for dose selection and methodology | Paul Ambrose | 20’ |
| | | Industry Perspective | Shampa Das | 20’ |

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|---|---|---|---|---|
| | | | (AstraZeneca) | |
| | | Discussion | | 20’ |

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|---|---|---|---|---|
| | 13:00-14-00 | Lunch | | |
| | 14:00-15:15 | Topic 6: replacing and interpreting clinical data | John Rex (AstraZeneca and F2G Ltd.) | |
| | | Viewpoints from industry | | 30’ |
| | | Discussion | | 45’ |
| | 15:15-15:45 | Summary and closing remarks | Co-Chairs and Rapporteur | |