EUFEPS BABP Network

The Global Bioequivalence Harmonisation Initiative

Program April 12, 2018

08:00 - 09:00 **Registration**

09:00 - 09:30 **Opening and welcome**

Erem Bilensoy, EUFEPS President, Ankara TR
Tomas Salmonson, European Medicines Agency, Uppsala S
Mehul Mehta, US Food and Drug Administration, Silver Spring MD USA
Introduction into the conference
Henning Blume, SocraTec S&C, Oberursel DE

9:30 – 13:00

Session I: Outcome summary and tying up loose ends of 2nd GBHI conference 2016 in Rockville/USA

Session co-chairs:
Henning Blume, SocraTec C&S, Oberursel DE
Mei-Ling Chen, Washington DC USA

Prodrugs and compounds with pre-systemic extraction

Conclusions from previous discussions at GBHI 2016 and open issues
tbd

Suggestions for further harmonization of remaining open issues
Henning Blume, SocraTec C&S, Oberursel DE

Scaling procedure and adaptive design(s)

Conclusions from previous discussions at GBHI 2016 and open issues
Andreas Brandt, BfArM, Bonn DE

Suggestions for further harmonization of remaining open issues
Lazlo Endrenyi, University Toronto CAN

Exclusion of PK data in BE assessment

Conclusion from previous discussions at GBHI 2016 and open issues
Liang Zhao, FDA, Silver Spring MD USA

Suggestions for further harmonization of remaining open issues
Keith D. Gallicano, Novum Pharmaceutical Research, Pittsburgh USA

14:00 – 18:30

Session II: Necessity of multiple dose studies in BE testing

Session co-chairs:
Gerald Beuerle, Teva, Ulm DE
Nilufer Tampal, US-FDA, Silver Spring MD USA

Introduction to Session II:

Similarities and differences between international guidelines
Gerald Beuerle, Teva, Ulm DE

Justification of the current regulatory approach by US FDA including a general waiver of multiple dose studies in BE assessment
Nilufer Tampal, US-FDA, Silver Spring MD USA

Justification of the current regulatory approach by EMA prohibiting the extrapolation of single dose BE to steady state in many cases
Alfredo Garcia, Agencia Española de Medicamentos, Madrid ES

Invited Presentations:

Scientific arguments in favor and against the requirement to perform steady state studies for MR products
Murray Ducharme, Learn/Confirm, Montreal CAN

Primary and secondary PK metrics for evaluation of steady state studies, C_{min} vs. C_τ, relevance of C_{min}/C_τ or fluctuation for bioequivalence assessment
Helmut Schütz, BEBAC, Vienna AU

Alternatives to steady state studies: Modelling/simulation or use of further parameters (e.g. partial AUC or plateau time) to better characterize plasma profiles after single dose administration
Yu Chung Tsang, Apotex, Toronto CAN

Overall Discussion

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8:00 – 12:00

Session III: BE of Transdermal Delivery Systems
Session co-chairs:
Barbara Schug, SocraTec R&D, Oberursel DE
Mehul Mehta, US Food and Drug Administration, Silver Spring MD USA

Introduction to Session III:

Bioequivalence and patch adhesion: similarities and differences between international guidelines
Barbara Schug, SocraTec R&D, Oberursel DE

Scientific arguments for the US perspective
Robert Lionberger, FDA, Silver Spring MD USA

Scientific arguments for the European perspective
Janet Schriever, BfArM, Bonn DE

Invited Presentations:

Necessity of multiple dose studies in case of patches with specific properties, i.e. formation of skin depots and varying dosing intervals (e.g. 3 vs. 4 days)
Björn Schurad/ Luye Pharma, Miesbach DE

Patch adhesion studies: evaluation and statistics
tbd.

Skin irritation and sensitization studies: a medical appraisal of the currently applied guidelines
Walter Wigger-Alberti, Bioskin, Hamburg DE

Panel discussion with introductory statements

US-FDA perspective: *Luke Markham, FDA, Silver Spring MD USA*

EU regulatory authorities' perspective: tbd.

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13:00 – 17:00

Session IV: **Liposomal parenteral preparations**

Session co-chairs:
Wenlei Jiang, US-FDA, Silver Spring MD USA
Henrike Potthast, BfArM, Bonn DE

Introduction to Session IV:

General concept for BE assessment of liposomal parenterals: which pharmacokinetic processes are determining?
tbd

North American regulatory authority's current regulatory thinking
Wenlei Jiang, US-FDA, Silver Spring MD USA

European regulatory authority's current regulatory thinking
Henrike Potthast, BfArM, Bonn DE

Invited Presentations:

Necessity of determination of free and encapsulated (and total) drug, e.g. doxorubicin
tbd)

Relevance of non- dose-proportional PK and body surface-area adjusted dosing for BE assessment: intra-individual exposure comparison and extrapolation between indications
tbd

Generic liposome products: adequate bioequivalence criteria and therapeutic implications
Daan Crommelin, Utrecht University, Amsterdam, The Netherlands

Final Discussion and closing remarks