

c	B	G	
	<i>M</i>	<i>E</i>	<i>B</i>

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2nd EMA Workshop on Biosimilar Monoclonal Antibodies

Leon van Aerts

Session 1 Non-clinical Issues

Introduction

Aim of non-clinical studies in biosimilarity approach

- To establish similar biological activity, potentially affecting efficacy and safety based on non-clinical data

Key issues in discussion on draft guideline

- High species-specificity triggered discussion on appropriateness of non-clinical *in vivo* studies
- Areas of interest include PD, PK and safety
- Discussion mostly focussed on safety

Topics in non-clinical session

- Off-target toxicity
 - What would constitute off-target toxicity
 - Can it be expected?
 - Can it be detected?
- Risk-based approach
 - Is it appropriate within the context of a biosimilar approach?
 - What are the risks and how do we assess them?
 - What is needed non-clinically?



After introductory presentations, please, participate in discussion

c	B	G	
	<i>M</i>	<i>E</i>	<i>B</i>