2017 BioSafe European Annual General Membership Meeting
November 14th & 15th, 2017
Hosted by GSK

Tuesday, November 14th		
8:00-8:30 AM	**Coffee & Registration**	
8:30 -8:45 AM	**Welcome and Opening Remarks**	
8:45-10:30 AM	**Session 1: Immunogenicity and Immune-mediated Findings** **Co-Chairs: Sven Kronenberg, Roche and Lucinda Weir, GSK**	
	Update on immune-mediated discussions in Industry	Curtis Maier, GSK
	Immunogenicity risk assessment and mitigation during preclinical stage of drug development	Vibha Jawa, Merck
	Evaluation of in vitro/in vivo predictive immunogenicity tools: preclinical vs clinical data from the Roche portfolio	Katharine Bray-French/Antonio Iglesias, Roche
	Preclinical evaluation of GITR agonist antibody immunogenicity and associated risks	Amy Beebe, Merck
	Clinical management of immune-mediated findings	Duncan Richards, GSK
10:30-11:00AM	**Coffee Break**	
11:00-12:45 PM	**Session 2: Advanced Therapy Medicinal Products** **Co-Chairs: Peter Ulrich, Novartis and Rajni Fagg, GSK**	
	Intro: news from the GCT world	Peter Ulrich, Novartis
	Update on CTL019 US approval	Peter Ulrich, Novartis
	Non-clinical safety strategy for first-in-human clinical trials with anti-glypican-3/CD3 T-Cell redirecting bispecific antibody (ERY974)	Shun-ichiro Komatsu, Chugai Pharmaceutical Co. Ltd.
	Overview for the need to determine on target/ off-target tissue expression	Esther Sutter, Novartis
	Vector Safety	Dr Theresa Wardell, Oxford BioMedica
12:45-1:30 PM	**Lunch**	

1:30-2:30 PM	**Breakout Sessions**	
2:30-3:30 PM	**Breakout Session Recap/Discussions**	
3:30-4:00 PM	**Coffee Break**	
4:00-6:00PM	**Session 3: Relevance and Limitations of NHP Studies for Human Safety and PK/PD Prediction in Man** **Co-chairs: Wolfgang Richter, Roche and Andrea Kiessling, UCB**	
	Safety testing of monoclonal antibodies in non-human primates: case studies highlighting their important impact on human risk assessment	Frank Brennan, UCB
	Translational PKPD from monkey to man - possibilities and limitations	Antje Walz, Roche
	NHP Studies for Nonclinical Assessment of BiTE® Antibody Constructs	Benno Rattel, Amgen
	Challenges of preclinical safety strategies and assessments for non cross-reactive peptide-based immunotherapies	Estelle Marrer-Berger, Roche and Andrea Kiessling, UCB
6:00 PM	Closing Remarks, housekeeping	
	Conference Dinner	

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Wednesday, November 15th		
8:00-8:30 AM	**Coffee and Registration**	
8:30-10:15 AM	**Session 4: PK and Safety of PEGylated Proteins – What's New?** **Co-Chairs: Rikke Hvid Lindecrona, Novo Nordisk and Andreas Baumann, Bayer**	
	Introduction	Andreas Baumann, Bayer
	PK, Distribution and Excretion of large PEGs (case example)	Andreas Baumann, Bayer
	Cimzia Juvenile tox case study	Alison Wolfreys, UCB
	Learnings from recent regulatory submission with pegylated coagulation factor IX (PK and safety)	Helene Jacobsen and Inga Bjørnsdottir Novo Nordisk
	Half-life extension strategies—moving beyond PEG	Kevin Brady, UCB
	Panel Discussion	
10:15-10:45 AM	**Coffee Break**	
10:45-12:30 PM	**Session 5: Preparing for Early Clinical Trials—What has Changed in the new EMA Guidance and How do we Respond** **Chair: Jay Tibbitts, AbbVie**	
	Update on the 2017 EMA Guideline for FIH and early clinical trials followed by discussion of changes and their impact.	Jay Tibbitts, AbbVie
	Case studies of FIH dosing strategies with focus on non-MABEL approaches and impact of new EMA guidance on strategy	
12:30-1:30 PM	**Lunch**	
1:30-3:30 PM	**Session 6 CMC Aspects on Nonclinical Programs** **Co-chairs: Peter Ulrich, Novartis and Andrea Kiessling, UCB**	

	CMC aspects of advanced therapy medicinal products and their impact on safety /efficacy (cell and gene therapy):	Florence Salmon, Novartis
3:30 PM	**Closing Remarks and Adjourn**	