2024 BioSafe Annual Meeting
May 20-22nd, 2024
213 E Grand Ave, South San Francisco, CA, Merck Research Laboratories

(All times in Pacific Daylight Time)

Monday, May 20		
12.00-1.00 PM	Registration	
1:00 – 1:15 PM	BioSafe Annual Meeting Welcome & Opening Remarks	Sean Ottinger (Novartis), 2024 GMM chair; Sam Gunter (BIO); Mike Oropallo (Merck, host)
	Message from the BioSafe Co-Leads	Wendy Freebern (Johnson and Johnson) & Sean Ottinger (Novartis), BioSafe Co-leads
Session 1: Novel Topics in Cell Therapy 1:15-3:10 PM Chairs: Cam Holland (Johnson and Johnson), Amanda Lucchini (Labcorp)		
1:15 PM	Emerging Topics and Trends in Cell Therapy	Cam Holland (Johnson and Johnson) and Amanda Lucchini (Labcorp)
1:25 PM	Regulatory considerations for the nonclinical development of CAR T cell therapies for non-malignant indications	Mondona McCann (CBER, FDA)
1:40 PM	Nonclinical Strategies in De-Risking Armored Cell Therapies	Di Zhang (Takeda)
2:05 PM	Tumorigenicity Evaluation of Cellular-Based Products Derived from Induced Pluripotent Stem Cells or Embryonic Stem Cells	Norman Kim (BlueRock)
2:30 PM	In Vivo Car T Cells	Christina Chaivorapol (Sana)
2:55 PM	Questions	All Speakers
3:15 PM	Coffee Break	
Session 2: Gene Therapy 3:45-5:10 PM Chairs: Eloise Hudry (Novartis), Jessica Lynch (Johnson and Johnson)		
3:45 PM	BIO CGT Activities Overview and Feedback from CGT FDA Meeting with CBER	Nicholas Buss (Akouos)

4:00 PM	Viral Integration and Safety	Keith Mansfield (Novartis)
4:25 PM	Off-Target Editing Characterization form Gene Therapy / Off-Target Assessments	Kathleen Meyer (Sangamo)
4:50 PM	Vertical Transmission for Non-Viral (LNP) Systemic Cas9 Gene Editors	Jonathan Phillips (Intelia)
5:15 – 5:30 PM	Panel Discussion with Audience Questions	All speakers
Open Night		
Tuesday, May 21		
7:45 AM	Breakfast	
Session 3: Manage Your Shipment to the Right Destination: Challenging Delivery of Delicate and Complex Biologics to Specialized Tissues 8:30-10:20 AM		

Chairs: Ulrike Hopfer (Roche), Lori Aschenbrenner (Labcorp), James Smith (Boehringer Ingelheim)		
8:30 AM	Aerosolization of Biologics for Orally Inhaled Drug Products	Emily Resseguie (Labcorp)
8:55 AM	Impact of Change in Formulation on the Toxicology of Inhaled Protein	Ian Wallace (AstraZeneca)
9:20 AM	Early-Stage Assessment of Stability and Pharmacokinetics as well as Impact of Biotransformation Products of Complex Next Generation Targeted Immunocytokines	Matthias Fueth (Roche)
9:40 AM	IV to Intravesical: Unlocking the Potential of EV in Non-Muscle-Invasive Bladder Cancer (NMIBC)	Chris Carosino (Pfizer)
10:00 AM	Panel Discussion with Audience Questions	All speakers
10:20 AM	Break	
Session 4: Oligos 10:30-12:30 PM Chairs: Claire Weekes (GSK), Onyi Irrechukwu (Johnson and Johnson)		
10:30 AM	Introduction	Onyi Irrechukwu (Johnson and Johnson)

10:35 AM	Nonclinical Development of Oligonucleotides	Mike Templin (Charles River Laboratories)
11:05 AM	Learnings from Development of Bepirovirsen for HBV	Steve Hood (GSK)
11:35 AM	CNS Delivery of RNAs Using a Novel Hybrid-Lipid Nanoparticle Technology	Mohammad Ali Amini (QurCan Therapeutics)
12:05 AM	Development of a Novel Muscle Targeted Antibody Oligonucleotide Conjugate for the Treatment of Myotonic Dystrophy Type	Maria Hedlund (Avidity Biosciences)
12:30 PM	Lunch	
Session 5: Indications Specific Considerations for Biologics 1:30-3:30 PM Chairs: Bindu Bennet (AstraZeneca), Mike Oropallo (Merck)		
1:30 PM	Rare Disease Strategy Through the Perspective of a Thyroid Eye Disease Patient	Hollie Skaggs (Amgen)
1:45 PM	Overview of Modality Specific Challenges for TCEs and ADCs	Rebecca Watson (Novartis)
2:00 PM	Breakout sessions separately for each modality (35 min) Summary of breakout sessions (20 min)	
3:00 PM	TCE/ADC – Challenges and Nonclinical Safety Assessment Framework in Autoimmune Indications	Ijee Uzoma (FDA)
3:30 PM	Break	
Session 6: Antibody-Drug Conjugates State of the Union **3:45-5:30 PM** Chairs: Smita Salian-Mehta (Gilead), Chandrashekhar Korgaonkar (Regeneron)		
3:45 PM	Overview and Challenges of ADCs	Carrie Dornan (Gilead)
4:05 PM	Alternative Methodology for ADCs	Michael Oropallo (Merck)
4:25 PM	Key Factors in the Translation of ADCs: From Mouse Models to FIH Study Design	Brooke Rock (Amgen)
4:55 PM	A Tale of Two ADCs	Whitney Helms (Loxo Oncology)
5:15 – 5:30 PM	Questions	All speakers

6:00 PM	Reception	
Wednesday, May 22		
8:00 AM	Breakfast	
Session 7: Extended joint session with HESI (Health and Environmental Sciences Institute) ImmunoSafety Technical Committee 8:30-12:00 PM Chairs: Marie-Soleil Piche (Charles River Laboratories), Wendy Freebern (J&J Innovative Medicines)		
8:30 AM	HESI ITC - Who are we?	Shermaine Mitchell-Ryan
8:40 AM	Integrating the I's: Immunotoxicology, Immunopharmacology & Immunopathology in Drug Discovery and Development	Intro: Wendy Freebern
		Challenges of Immunopath, establishing adversity and incorporating and integrating immunopath as it relates to AAV/cell: Tracey Papenfuss (StageBio) (40 min)
		Case study vignette: Impact of Immunopharmacology on a Toxicity Study: Courtni Newsome (BMS)
9:50 AM	Quick Stretch Break, please leave room only if necessary	
10:00 AM	Industry Wide Perspectives: Impact of Antibody Fc Engineering on Translational Pharmacology & Safety	Frank Brennan (UCB), Ryan Polli (Novartis) & Jean Sathish (Pfizer)
10:50	Break	
11:10	Nearly 2 decades post TGenero: New Perspectives and Guidance on the When or Ifs of Cytokine Release Hazard ID	Marie-Soleil Piche & Mark Collinge (Pfizer)
12:10	**Feeback from General Membership and Closing Remarks**	