Tuesday, November 8, 2022

Developing New Therapies for Patients with MM

9:00–9:30 AM	**SESSION 1: WELCOME**	
9:00–9:15 AM	*Nikhil Munshi*	
9:15–9:30 AM	*Bindu Kanapuru*	
9:30 AM-11:30 AM	**SESSION 2: TRIAL DESIGN CONSIDERATIONS FOR NOVEL THERAPIES**	
9:30–9:45 AM	Current drug development landscape	*Vincent Rajkumar*
9:45–10:00 AM	Regulatory Considerations for novel drug development in MM	*Alex Schwarsin*
10:00-11:15 AM	Panel Discussion	
	MODERATOR: *Vincent Rajkumar*	
	PANELISTS: *Ajai Chari, Sagar Lonial, Shaji Kumar, Philippe Moreau, Bindu Kanapuru, Andrea Baines, Alex Schwarsin, Jonathan Vallejo, Rod Humerickhouse*	
11:15 AM - 11:30 AM	**BREAK**	
11:30 AM - 1:00 PM	**SESSION 3: ENDPOINTS**	
11:30-11:45 AM	Current landscape and perspective on alternate endpoints development	*Saad Usmani*
11:45-12:00 PM	Regulatory considerations for endpoints (PFS, OS, MRD, QoL)	*Nicholas Richardson*
12:00-1:00 PM	Panel Discussion	
	MODERATOR: *Tom Martin*	
	PANELISTS: *Antje Hoering, Faith Davies, Jesus San Miguel, Qing Xu, Nicole Gormley, Vishal Bhatnagar, Jim Omel, Kevin Liu*	
1:00 - 1:45 PM	**LUNCH**	

1:45 PM–3:15 PM	**SESSION 4: EXTERNAL VALIDITY OF MM CLINICAL TRIALS**	
1:45–2:00 PM	FDA Clinical Context: Why is it important in Multiple Myeloma?	*Rachel Ershler*
2:00–3:15 PM	Panel Discussion	
	MODERATOR: *Sundar Jagannath*	
	PANELISTS: *Sham Mailankody, Larry Anderson, Natalie Callander, Bindu Kanapuru, Rachel Ershler, David Mitchell, Craig Tendler, Orlando Bueno*	
3:15 PM–4:00 PM	**SESSION 5: REAL WORLD DATA AND RWE**	
3:15–3:30 PM	Clinical Evidence Generation and Use of RWD: An FDA Oncology Perspective	*Catherine Lerro*
3:30–4:00 PM	Panel Discussion: Real World Data and RWE	
	MODERATOR: *Faith Davies*	
	PANELISTS: *Ravi Vij, Elizabeth O'Donnell, Jeff Zonder, Jonathon Vallejo, Nicole Gormley, Catherine Lerro, David Mitchell, Nathan Hill*	
4:00–4:15 PM	**WRAP-UP OF DAY 1**	

Wednesday, November 9, 2022

Disease Setting Considerations for Novel Drug Development

9:00-9:10 AM	**WELCOME AND RECAP DAY 1**	
9:10–10:15 AM	**SESSION 6: DRUG DEVELOPMENT IN NEWLY DIAGNOSED MM**	
9:10–9:25 AM	Considerations for newly diagnosed transplant eligible MM and transplant ineligible MM; Unmet need in the newly diagnosed patient population	*Ken Anderson*
9:25–10:15 AM	Panel Discussion	
	MODERATOR: *Ken Anderson*	
	PANELISTS: *Vincent Rajkumar, Ajay Nooka, Noopur Raje, Maria-Victoria Mateos, Bindu Kanapuru, Andrea Baines, Erik Vandendries*	
10:15–10:30 AM	**BREAK**	
10:30–11:30 AM	**SESSION 7: MAINTENANCE THERAPY IN MM**	
10:30–11:30 PM	Panel Discussion	
	MODERATOR: *Philippe Moreau*	
	PANELISTS: *Krina Patel, Joshua Richter, Saad Usmani, Bindu Kanapuru, Rachel Ershler, Antonio Palumbo*	
11:30 AM–12:15 PM	**LUNCH**	

12:15–2:00 PM	**SESSION 8: DRUG DEVELOPMENT IN RRMM**	
12:15–12:30 PM	Defining the patient population for RRMM trials-where is the need?	*Sagar Lonial*
12:30–12:45 PM	Regulatory considerations for designing trials in biomarker selected patient populations	*Pat DeMoss*
12:45–1:15 PM	Viewpoint: Patient populations for trials defined by prior lines or by receipt of specific class of agent or both	
12:45–12:55 PM	*Noopur Raje*	
12:55–1:05 PM	*Philippe Moreau*	
1:05–1:15 PM	Conclusion	
1:15–2:00 PM	Panel Discussion	
	MODERATOR: *Nikhil Munshi*	
	PANELISTS: *Jesus San Miguel, Kenneth Anderson, Robert Orlowski, Carol Ann Huff, Nicole Gormley, Andrea Baines, Jim Omel, Tina Nielsen*	
2:00–2:15 PM	**BREAK**	
2:15–3:15 PM	**SESSION 9: SMOLDERING MM**	
2:15–2:30 PM	Defining a patient population for smoldering MM trials-Overview of the current definitions	*Shaji Kumar*
2:30–3:15 PM	Panel Discussion	
	MODERATOR: *Maria-Victoria Mateos*	
	PANELISTS: *Irene Ghobrial, Elizabet Manasanach, Peter Voorhees, Nicole Gormley, Rachel Ershler, Robin Carson*	
3:15–3:30 PM	**WORKSHOP WRAP UP**	
	WORKSHOP CHAIRS: *Nicole Gormley, Nikhil Munshi*	
3:30–3:45 PM	**NEXT STEPS**	