Welcome
Richard Pazdur, MD, FDA
INTRO:
Nicole Gormley, MD, FDA
WORKSHOP OVERVIEW:
Ken Anderson, MD, FAACR
Dana-Farber Cancer Institute
Ruixiao Lu, PhD
Alumis Inc./ASA

Session 1: Trial Design Considerations for Optimal Assessment of Overall Survival
MODERATOR:
Ken Anderson, MD, FAACR
Dana-Farber Cancer Institute
OVERVIEW OF RECOMMENDATIONS
SESSION CHAIR:
Ruben Mesa, MD, Atrium Health
ADDITIONAL PANELISTS:
• R. Angelo de Claro, MD, FDA
• Xin Gao, PhD, FDA
• Jaleh Fallah, MD, FDA
• Jian Zhao, PhD, FDA
• Boris Freidlin, PhD, NCI
• George Demetri, MD, FAACR, Dana-Farber Cancer Institute
• Laura J. Esserman, MD, MBA, FAACR, UCSF
• Qi Xia, PhD, AbbVie

Session 2: Overall Survival as a Pre-specified Endpoint
MODERATOR:
Lisa Rodriguez, PhD, FDA
INTRO:
Qing Xu, PhD, FDA
OVERVIEW OF RECOMMENDATIONS
SESSION CHAIR:
Steven Snapinn, PhD, FASA
Seattle-Quilcene Biostatistics LLC
ADDITIONAL PANELISTS:
• Wenjuan Gu, PhD, FDA
• Bindu Kanapuru, MD, FDA
• Paz Vellanki, MD, PhD, FDA
• Grzegorz Nowakowski, MD, Mayo Clinic
• Qian Shi, PhD, Mayo Clinic
• Emmanuel Zuber, PhD, Novartis Pharma AG

Session 3: Post-hoc Analyses of Overall Survival Endpoints
MODERATOR:
Jonathon Vallejo, PhD, FDA
INTRO:
Qing Xu, PhD, FDA
OVERVIEW OF RECOMMENDATIONS
SESSION CHAIR:
George Demetri, MD, FAACR
Dana-Farber Cancer Institute
ADDITIONAL PANELISTS:
• Pallavi Mishra-Kalyani, PhD, FDA
• Nicholas Richardson, DO, MPH, FDA
• Cong Chen, PhD, FASA, Merck
• David Mitchell, Patient Advocate
• Grzegorz Nowakowski, MD, Mayo Clinic
• Craig Tendler, MD, Janssen of Johnson & Johnson

Session 4: Subgroup Considerations
MODERATOR:
Anup Amatya, PhD, FDA
INTRO:
Michael Shan, PhD, Bayer

Session 5: Incorporation of Overall Survival into the Benefit-Risk Assessment
MODERATOR:
Nicole Gormley, MD, FDA
OVERVIEW OF RECOMMENDATIONS
SESSION CHAIR:
George Demetri, MD, FAACR
Dana-Farber Cancer Institute
ADDITIONAL PANELISTS:
• Pallavi Mishra-Kalyani, PhD, FDA
• Nicholas Richardson, DO, MPH, FDA
• Cong Chen, PhD, FASA, Merck
• David Mitchell, Patient Advocate
• Grzegorz Nowakowski, MD, Mayo Clinic
• Craig Tendler, MD, Janssen of Johnson & Johnson

Summary and Closing Remarks
Ken Anderson, MD, FAACR
Dana-Farber Cancer Institute
Lisa Rodriguez, PhD, FDA