

2017 CTEP EARLY DRUG DEVELOPMENT MEETING

September 25–26, 2017
 NCI Shady Grove
 Conference Room TE406

MEETING AGENDA

MONDAY, SEPTEMBER 25, 2017

8:30 AM	<i>Welcome/Introduction</i> John Wright, Investigational Drug Branch, Cancer Therapy Evaluation Program, National Cancer Institute
CTEP-SPONSORED EARLY PHASE I STUDIES: CLINICAL TRIAL STATUS UPDATE SESSION <i>Moderators: Naoko Takebe, DCTD, Richard Piekarz, IDB, and Helen Chen, IDB, CTEP, NCI</i>	
8:35–8:50 AM	A Phase I Study of Aurora Kinase Inhibitor Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors Laura Goff, Vanderbilt University
8:50–9:05 AM	A Phase I/II Study of Talazoparib (BMN673), an Oral Poly(ADP-Ribose) Polymerase Inhibitor, Plus Temozolomide in Children with Refractory or Recurrent Malignancies Eric Schafer, Texas Children’s Cancer Center
9:05–9:20 AM	A Phase I Study of WEE1 Inhibitor AZD1775 with Radiation and Temozolomide in Patients with Newly Diagnosed Glioblastoma and Evaluation of Intratumoral Drug Distribution in Patients with Recurrent Glioblastoma Brian Alexander, Dana-Farber Cancer Institute
9:20– 9:35 AM	A Phase I and Phase II and Re-Treatment Study of Selumetinib (AZD6244) for Recurrent or Refractory Pediatric Low Grade Glioma Jason Fangusaro, Northwestern University Lurie Children’s Hospital
9:35– 9:50 AM	Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with Dabrafenib in Patients with BRAF Mutant Cancer Alain Agazi, University of California, San Francisco
9:50–10:10 AM:	PANEL DISCUSSION
10:10–10:30 AM:	BREAK

CTEP-SPONSORED EARLY PHASE II STUDIES: CLINICAL TRIAL STATUS UPDATE SESSION (CONTINUED)*Moderators: Austin Doyle IDB, Helen Chen IDB, and Howard Streicher, IDB, CTEP, NCI*

10:30–10:45 AM	A Phase II Trial of Gemcitabine-Eribulin (GE) in Cisplatin Ineligible Patients with Advanced or Unresectable Urothelial Carcinoma of the Bladder. Sarmad Sadeghi, University of Southern California
10:45–11:00 AM	A Randomized Phase II Study of Sequential Biotherapy with Aflibercept and High Dose IL-2 versus High Dose IL-2 Alone in Patient with Inoperable Stage III or Stage IV Melanoma: Efficacy and Biomarker Study Ahmad Tarhini, Cleveland Clinic
11:00–11:15 AM	A Randomized Phase IIB Evaluation of Weekly Paclitaxel Plus Pazopanib Versus Weekly Paclitaxel Plus Placebo in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma Debra Richardson, University of Texas Southwestern Medical Center
11:15–11:30 AM	A Randomized Phase II Trial of Single Agent MEK Inhibitor Trametinib (GSK1120212) versus 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer (SWOG 1310) Richard Kim, Moffitt Cancer Center
11:30–11:45 AM	Randomized Phase II Study Comparing Cabozantinib with Commercially Supplied Sunitinib in Patients with Previously Untreated Locally Advanced or Metastatic Renal Cell Carcinoma Tian Zhang, Duke University
11:45 AM–12:05 PM	PANEL DISCUSSION
12:05–1:30 PM	LUNCH BREAK (Attendees on own) <i>There will be a Closed ETCTN Meeting for UM1 PIs in Seminar Room 110.</i>

CTEP-SPONSORED EARLY PHASE IMMUNOTHERAPY STUDIES; CLINICAL TRIAL STATUS UPDATE SESSION*Moderators: Elad Sharon and Howard Streicher, IDB, CTEP, NCI*

1:30–1:55 PM	Keynote Lecture: Predictive Biomarkers for Checkpoint Inhibitor-based Immunotherapy Michael Atkins, Georgetown University
1:55–2:10 PM	A Phase I Study with an Expansion Cohort of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma Catherine Diefenbach, New York University
2:10–2:25 PM	A Phase I Trial of MK-3475 plus Ziv-Aflibercept in Patients with Advanced Solid Tumors Stephen Hodi, Dana-Farber Cancer Center
2:25– 2:40 PM	A Multi-Institutional Phase II Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Cancer Cathy Eng, MD Anderson Cancer Center
2:40–2:55 PM	PANEL DISCUSSION

TRANSLATIONAL SCIENCE-FROM ASSAY DEVELOPMENT TO CLINICAL IMPLEMENTATION
Moderators: Alice Chen, ECTDP, DCTD, NCI and Tracy Lively, CDP, DCTD, NCI

2:55–3:15 PM	Case Study 1: Clinical and Translational Pharmacodynamics Ralph Parchment, Clinical Pharmacodynamics Biomarker Program Frederick National Laboratory for Cancer Research
3:15–3:35 PM	Suitability Factors of Core Needle Biopsies for Pharmacodynamic Studies Katherine Ferry-Galow, Clinical Pharmacodynamics Biomarker Program, Frederick National Laboratory for Cancer Research
3:35–3:55 PM	Improving Biopsies for Research Purposes at the DTC Alice Chen, Early Clinical Trials Development Program, Division of Cancer Treatment and Diagnosis, NCI
3:55–4:05 PM	Case Study 2: What It Takes to Develop Good Assays Tracy Lively, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, NCI
4:05–4:25 PM	A Phase I Trial of M7824, a Dual Anti PD-L1 and TGF beta TRAP in Patients with Advanced Malignancies Julius Strauss, Laboratory of Tumor Immunology and Biology Center for Cancer Research, NCI
4:25–4:45 PM	Pharmacodynamic and Pharmacokinetic Analyses of M7824 Trial to Provide Data on the Mechanism of Action and Dose-Dependent Activity in the Phase I Study Liang Cao, Genetics Branch, Center for Cancer Research, NCI
4:45–5:30 PM	PANEL DISCUSSION
5:30 PM	ADJOURN

TUESDAY, SEPTEMBER 26, 2017

8:30–8:35 AM	<i>Introduction</i>
EDUCATION SESSION: ADVANCES IN THE BIOLOGY AND TREATMENT/IMMUNOTHERAPY OF SOFT-TISSUE SARCOMAS <i>Moderator: Fernanda Araldez, IDB, NCI</i>	
8:35–8:55 AM	Novel Drugs and Targets: What's Next in the World of Sarcoma Gary Schwartz, Columbia University
8:55–9:15 AM	Sarcoma Pathology: Diagnostic Approach for Optimal Therapy Leona Doyle, Brigham & Women's Hospital
9:15–9:30 AM	Sarcoma Metabolism and Treatment Initiatives with Anti-Metabolic Agents Brian Van Tine, Washington University
9:30–9:45 AM	Epigenetic Therapies for the Investigational Treatment of Sarcomas Edwin Choy, Harvard University

9:45–10:05 AM	Incorporating Immunotherapeutic Strategies in Sarcoma Treatment I: Checkpoint and CTLA4 Inhibitors (Including Update of NCI-Sponsored Trial; Alliance A091401): A Multi-Center Phase II Study of Nivolumab +/- Ipilimumab for Patients with Metastatic Sarcoma. Sandra D'Angelo, Memorial Sloan-Kettering Cancer Center
10:05–10:25 AM	Incorporating Immunotherapeutic Strategies in Sarcoma Treatment II: Vaccines and Cellular Therapies Seth Pollack, Fred Hutchinson Cancer Center
10:25–10:40 AM	Treatment Advances in GIST Margaret von Mehren, Fox Chase Cancer Center
10:40 –10:55 AM	PANEL DISCUSSION
10:55 –11:10 AM	BREAK
ELEVENTH ANNUAL MICHAEL C. CHRISTIAN ONCOLOGY DRUG DEVELOPMENT AWARD & LECTURE	
11:10–11:20 AM	<i>Introduction</i> Jeff Abrams, CTEP, NCI
11:20–11:30 AM	Presentation of Award Michael C. Christian and John Wright, IDB, CTEP, NCI
11:30 AM–12:00 PM	AWARDEE LECTURE
12:00 PM:	ADJOURN