

2018 CTEP EARLY DRUG DEVELOPMENT MEETING

October 1-2, 2018

NCI Shady Grove

Conference Room TE406

MEETING AGENDA

MONDAY, OCTOBER 1, 2018

8:30 AM	<p><i>Welcome/Introduction</i> John Wright, Investigational Drug Branch, Cancer Therapy Evaluation Program, National Cancer Institute</p>
<p>CTEP-SPONSORED EARLY PHASE IMMUNOTHERAPY STUDIES: CLINICAL TRIAL STATUS UPDATE SESSION <i>Moderators: Elad Sharon and Howard Streicher, IDB, CTEP, NCI</i></p>	
8:35 – 9:00 AM	<p>Keynote Lecture: T-cell Therapies for Lymphoma – CARs and Beyond Catherine Bollard, Children's National Health System</p>
9:00 – 9:15 AM	<p>A Safety and Preliminary Efficacy Trial of MK-3475 (Pembrolizumab; anti-PD-1) in Children with Recurrent Progressive or Refractory Diffuse Intrinsic Pontine Gliomas (PBTC-045) Eugene Hwang, Children's National Health System</p>
9:15 – 9:30 AM	<p>A Phase I Study of Recombinant Interleukin-15 in Combination with Checkpoint Inhibitors Nivolumab and Ipilimumab in People with Refractory Cancers Geraldine O'Sullivan Coyne, Center for Cancer Research, NCI</p>
9:30 – 9:45 AM	<p>A Phase I Study of Ipilimumab in Combination with Rituximab in Patients with Relapsed/Refractory Indolent Lymphoma Joseph Tuscano, University of California, Davis</p>
9:45 – 10:00 AM	<p>DART: Dual Anti-CTLA4 and Anti-PD-1 Blockade in Rare Tumors: Overview and Results of Neuroendocrine Cancer Arm Sandip Patel, University of California, San Diego</p>
10:00 – 10:15 AM	<p>A Phase 2 Study of Atezolizumab (MPDL3280A) in Combination with Bevacizumab in Patients with Recurrent, Persistent or Metastatic Cervical Cancer Claire Friedman, Memorial Sloan-Kettering Cancer Center</p>
10:15 – 10:30 AM	<p>A Phase I/Ib Study of Ipilimumab or Nivolumab in Patients with Relapsed Hematologic Malignancies after Allogeneic Hematopoietic Cell Transplantation Matthew Davids, Dana-Farber Cancer Center</p>
10:30 – 10:50 AM	PANEL DISCUSSION
10:50 – 11:00 AM	BREAK

CTEP-SPONSORED EARLY PHASE TRIALS EMPLOYING RADIATION THERAPY <i>Moderator: Charles Kunos and Helen Chen, IDB, CTEP, NCI</i>	
11:00 – 11:15 AM	Phase I and Pharmacology Study of Oral 5-Iodo-2-Pyrimidinone-2-Deoxyribose (IPdR) as Prodrug for IUdR-Mediated Tumor Radiosensitization in Gastrointestinal Cancers Timothy Kinsella, Rhode Island Hospital
11:15 – 11:30 AM	A COG Phase I Consortium Study of AZD1775 (MK-1775, Adavosertib) Concurrent with Local Radiation Therapy for the Treatment of Newly Diagnosed Children with Diffuse Intrinsic Pontine Gliomas Tabitha Cooney, University of California, San Francisco
11:30 – 11:45 AM	Phase II Study of MEDI4736 (Durvalumab) and Tremelimumab Alone or in Combination with High or Low-Dose Radiation in Metastatic Colorectal Cancer and NSCLC Jonathan Schoenfeld, Dana-Farber Cancer Center
11:45 AM – 12:15 PM	Keynote Lecture: New Strategies in Treating “Oligo” Metastases with Radiotherapy Ralph Weichselbaum, University of Chicago
12:15 – 12:30 PM	PANEL DISCUSSION
12:30 – 2:00 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 II STUDIES: CLINICAL TRIAL STATUS UPDATE SESSION <i>Moderators: Austin Doyle and Percy Ivy, IDB, CTEP, NCI</i>	
2:00 – 2:20 PM	A Phase III, Double Blind, Randomized, Placebo-Controlled Trial of Sorafenib in Desmoid Tumors or Aggressive Fibromatosis Mrinal Gounder, Memorial Sloan-Kettering Cancer Center
2:20 – 2:35 PM	A Phase II Trial of the MEK1/2 Inhibitor Selumetinib (AZD6244 Hydrogen Sulfate) in Adults with Neurofibromatosis Type I and Inoperable Plexiform Neurofibromas Andrea Gross, Center for Cancer Research, NCI
2:35 – 2:50 PM	A Phase 2 Study of Ibrutinib (PCI-32765) in Refractory Distant Metastatic Cutaneous Melanoma: Correlation of Biomarkers with Response and Resistance Stergios Moschos, University of North Carolina
2:50 – 3:10 PM	PANEL DISCUSSION
CTEP-SPONSORED EARLY PHASE I STUDIES; CLINICAL TRIAL STATUS UPDATE SESSION <i>Moderators: John Wright and Howard Streicher, IDB, CTEP, NCI</i>	
3:10 – 3:25 PM	A Phase I Study of Z-Endoxifen in Adults with Hormone Receptor Positive Solid Tumors Arjun Mitra, Center for Cancer Research, NCI
3:25 – 3:40 PM	A Phase I Study of Pomalidomide Given at the Time of Lymphocyte Recovery Following Induction Timed Sequential Chemotherapy with Cytarabine, Daunorubicin, and Etoposide (AcDVP16) in Patients with Newly Diagnosed Acute Myeloid Leukemia (AM) and High-Risk MDS Ivana Gojo, John Hopkins University
3:40 – 3:55 PM	A Phase 1 Study of Entinostat, an Oral Histone Deacetylase Inhibitor, in Pediatric Patients with Recurrent or Refractory Solid Tumors, Including CNS Tumors and Lymphoma (ADVL1513) Andrew Bukowski, UPMC Children's Hospital of Pittsburgh
3:55 – 4:10 PM	An Organ Dysfunction Consortium Phase I and Pharmacokinetic Single

	Agent Study of Romidepsin in Patients with Lymphoma, Chronic Lymphocytic Leukemia and Select Solid Tumors and Varying Degrees of Liver Dysfunction Roisin Connolly, Johns Hopkins University School of Medicine
4:10 – 4:30 PM	PANEL DISCUSSION
4:30 – 5:00 PM	GREVER FESTSCHRIFT
5:00 PM	ADJOURN

TUESDAY, OCTOBER 2, 2018

8:30 – 8:35 AM	<i>Introduction</i> John Wright, Investigational Drug Branch, Cancer Therapy Evaluation Program, National Cancer Institute
EDUCATION SESSION: ADVANCES IN THE BIOLOGY AND TREATMENT OF LUNG CANCERS Moderator: Jeff Moscow and Fernanda Arnaldez, IDB, CTEP, NCI	
8:35 – 8:55 AM	Novel Approaches for Treatment of EGFR Mutant Non-Small Cell Lung Cancer Greg Riely, Memorial Sloan-Kettering Cancer Center
8:55 – 9:10 AM	A Phase I Trial of AZD9291 (Osimertinib) and Necitumumab in EGFR-Mutant Non-Small Cell Lung Cancer after Progression on a Previous EGFR Tyrosine Kinase Inhibitor Jonathan Riess, City of Hope
9:10 – 9:30 AM	Preoperative and Postoperative Systemic Therapies in Lung Cancer Patrick Forde, Johns Hopkins University Cancer Center
9:30 – 9:50 AM	Immunotherapy Combination Initiatives for Metastatic, Advanced Stage Lung Cancer Hossein Borghaei, Fox Chase Cancer Center
9:50 – 10:05 AM	PANEL DISCUSSION
10:05 – 10:25 AM	Designing Clinical Trials to Identify Biomarkers in Lung Cancer Research Kurt Schalper, Yale University
10:25 – 10:45 AM	Immunotherapy and other Promising Therapeutic Strategies for Small Cell Lung Cancer Taofeek Owonikoko, Emory University
10:45 – 11:05 AM	PANEL DISCUSSION
11:05 – 11:15 AM	BREAK
TWELFTH ANNUAL MICHAEL C. CHRISTIAN ONCOLOGY DRUG DEVELOPMENT AWARD & LECTURE	
11:15 – 11:30 AM	<i>Introduction</i> Jeff Abrams, CTEP, NCI
11:30 – 11:40 AM	Presentation of Award Michael C. Christian and John Wright, IDB, CTEP, NCI
11:40 AM – 12:00 PM	AWARDEE LECTURE
12:00 PM	ADJOURN