



2019 CTEP EARLY DRUG DEVELOPMENT MEETING
October 17-18, 2019
NCI Shady Grove
Conference Room TE406
MEETING AGENDA

THURSDAY, OCTOBER 17, 2019

8:30 AM	<i>Welcome/Introduction</i> Jeff Moscow, Investigational Drug Branch (IDB), Cancer Therapy Evaluation Program (CTEP), National Cancer Institute (NCI)
UM1 BIOMARKER SUPPLEMENT SESSION/LESSONS LEARNED Moderators: Tracy Lively, DCTD, CDP, NCI and Jeff Moscow, IDB, CTEP, NCI	
8:35 – 8:40 AM	<i>Introduction/Background to Topic</i> Tracy Lively, Cancer Diagnosis Program, NCI Jeff Moscow, Investigational Drug Branch, Cancer Therapy Evaluation Program, NCI
8:40 – 8:55 AM	<i>Validation of Flow-Cytometry Biomarkers for ETCTN Immunotherapy Studies in Acute Leukemias</i> Leo Luznik, Johns Hopkins University Nina Lukinova, Cancer Diagnosis Program, NCI
8:55 – 9:10 AM	<i>Plasma Genomics as a Biomarker of Response</i> Geoff Oxnard, Dana-Farber Cancer Institute/Harvard Tawnya McKee, Cancer Diagnosis Program, NCI
9:10 – 9:25 AM	<i>Precision Oncology through Multiplex Testing for Antibody Drug Conjugate Targets</i> Funda Meric-Bernstam, MD Anderson Cancer Center Nina Lukinova, Cancer Diagnosis Program, NCI
9:25– 9:40 AM	<i>MEK inhibition on PD-L1 expression and CD8+ T cell infiltration in patients with cholangiocarcinoma</i> Bob Anders, Johns Hopkins University Nina Lukinova, Cancer Diagnosis Program, NCI
9:40 – 9:55 AM	<i>Development of a Rad51-based assay to determine the status of DNA repair by homologous recombination in tumor samples</i> Bose Kochupurakkal, Dana-Farber Cancer Institute/Harvard Percy Ivy, Investigational Drug Branch, CTEP, NCI

9:55 – 10:10 AM	Use of quantitative immunofluorescence (IF) to determine predictive cellular and protein biomarkers of clinical response to immune checkpoint blockade in cancer Jonathan Schoenfeld, Dana-Farber Cancer Institute/Harvard Magdalena Thurin, Cancer Diagnosis Program, NCI
10:10 – 10:30 AM	PANEL DISCUSSION
10:30 – 10:45 AM	BREAK
New NCI Initiatives Session Moderator: Jeff Moscow and Percy Ivy, IDB, CTEP, NCI	
10:45 – 11:30 AM	National Clinical Laboratory Network (NCLN) Tracy Lively, Cancer Diagnosis Program, NCI Chris Karlovich, Frederick National Laboratory for Cancer Research Katherine Ferry-Galow, Frederick National Laboratory for Cancer Research
11:30 – 12:00 PM	Experimental Therapeutics Clinical Trials Network (ETCTN) Interventional Radiology Working Group Lalitha Shankar, Cancer Imaging Program, NCI Percy Ivy, Investigational Drug Branch, CTEP, NCI
12:00 – 12:15 PM	PANEL DISCUSSION
12:15 – 1:30 PM	LUNCH BREAK (ATTENDEES ON OWN) <i>THERE WILL BE A CLOSED ETCTN MEETING FOR UM1 PIS IN SEMINAR 110</i>
CTEP-SPONSORED EARLY-PHASE IMMUNOTHERAPY STUDIES: CLINICAL TRIAL SESSION Moderators: Elad Sharon and Howard Streicher, IDB, CTEP, NCI	
1:30 – 1:55 PM	Keynote Lecture: Immunotherapy and Clinical Trial Design Lillian Siu, Princess Margaret Hospital
1:55 – 2:15 PM	Protocol # CITN11-01: Phase I Study of Neo-adjuvant RO7009789 Alone or Neo-adjuvant RO7009789 Plus Nab-Paclitaxel and Gemcitabine Followed by Adjuvant RO7009789 Plus Nab-Paclitaxel and Gemcitabine for Patients with Newly Diagnosed Resectable Pancreatic Carcinoma Mark O'Hara, University of Pennsylvania
2:15 – 2:35 PM	Protocol # CITN-12: Phase I Study of MK-3475 (Pembrolizumab) in Patients with Human Immunodeficiency Virus (HIV) and Relapsed/Refractory or Disseminated Malignant Neoplasm Thomas Uldrick, Fred Hutchinson Cancer Center
2:35 PM – 2:55 PM	Protocol # 10014: A Pilot Study of Atezolizumab (MPDL3280A) Following Adoptive Cell Transfer in Active Hematologic or Solid Tumor Malignancies Marcus Butler, Princess Margaret Hospital
2:55 – 3:15 PM	Protocol # CITN-07-FLT3L: A Phase II Trial of CDX-1401, a Dendritic Cell Targeting NY-ESO-1 Vaccine, in Patients with

	Malignant Melanoma Pre-Treated with Recombinant CDX-301, a Recombinant Human Flt3 Ligand Steven Fling, Fred Hutchinson Cancer Center
3:15 – 3:35 PM	Protocol # CITN-13: A Phase II Trial of MK-3475 (Pembrolizumab) and Interferon Gamma 1-b Combination Immunotherapy in Patients with Previously Treated Mycosis Fungoides and Sezary Syndrome (Treatment Group 1) and in Patients with Advanced Synovial Sarcoma (Treatment Group 2) Michael Khodadoust, Stanford University
3:35– 3:55 PM	Protocol # E4412 - A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma Catherine Diefenbach, Perlmutter Cancer Center at NYU Langone Health
3:55 – 4:15 PM	Protocol # 10104: A Randomized Phase 2 Study of Cabozantinib in Combination with Nivolumab in Advanced, Recurrent Metastatic Endometrial Cancer Stephanie Lheureux, Princess Margaret Hospital
4:15 – 4:35 PM	Protocol # 10005: A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Alveolar Soft Part Sarcoma Rafah Naqash, Developmental Therapeutics Clinic, NCI
4:35 – 5:00 PM	PANEL DISCUSSION
5:00 PM	ADJOURN

FRIDAY, OCTOBER 18, 2019

8:30 – 8:35 AM	<i>Introduction</i> Jeff Moscow, Investigational Drug Branch, CTEP, NCI
RADIOPHARMACEUTICAL SESSION	
MODERATOR: CHARLES KUNOS, IDB, CTEP, NCI	
8:35 – 8:55 AM	CTEP rollout of radiopharmaceutical clinical development Charles Kunos, Investigational Drug Branch, CTEP, NCI
8:55 – 9:15 AM	Radiopharmaceuticals – logistical considerations for IND supply under DCTD-held IND Rodney Howells, Pharmaceutical Management Branch, CTEP, NCI
9:15 – 9:35 AM	Personalized “Radiation Dosimetry for Targeted Radionuclide Therapy -The Needs and Means Jeff Buchsbaum, Cancer Imaging Program, NCI
9:35 – 9:55 AM	Molecular imaging in theranostics development Michael McDonald, Cancer Imaging Program, NCI
9:55 – 10:05 AM	PANEL DISCUSSION
CTEP PHASE I & II CLINICAL TRIALS UPDATE	
MODERATOR: PERCY IVY, IDB, CTEP, NCI AND MALCOLM SMITH, CIB, CTEP, NCI	

10:05 – 10:20 AM	Protocol # 9984: A Randomized Phase 2 Study of Cediranib in Combination with Olaparib Versus Olaparib Alone in Men with Metastatic Castration Resistant Prostate Cancer Joseph Kim, Yale University
10:20 – 10:35 AM	Protocol # 9771: Phase I Study of Veliparib (ABT-888), an Oral PARP Inhibitor, and M6620 (VX-970), an ATR Inhibitor, in Combination with Cisplatin in Patients with Refractory Solid Tumors Arjun Mitra, Developmental Therapeutics Clinic, NCI
10:35 – 10:50 AM	Protocol # ADVL1312: A Phase 1/2 Study of AZD1775 (MK-1775) in Combination with Oral Irinotecan in Children, Adolescents, and Young Adults with Relapsed or Refractory Solid Tumors Kristina Cole, Children's Hospital of Philadelphia
10:50 – 11:05 AM	Protocol # ADVL1622: Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors Srivandana Akshintala, New York University Medical Center
11:05 – 11:15 AM	PANEL DISCUSSION
THIRTEEN ANNUAL MICHAEL C. CHRISTIAN ONCOLOGY DRUG DEVELOPMENT AWARD & LECTURE	
11:15 – 11:25 AM	<i>Introduction</i> Jeff Moscow, Investigational Drug Branch, CTEP, NCI
11:25 – 11:35 AM	Presentation of Award Michael C. Christian and Jeff Moscow, IDB, CTEP, NCI
11:35 AM – 12:00 PM	AWARDEE LECTURE
12:00 PM	ADJOURN