



2020 CTEP EARLY DRUG DEVELOPMENT MEETING

October 15, 2020

DRAFT MEETING AGENDA

THURSDAY, OCTOBER 15, 2020

11:00 AM	<i>Welcome/Introduction</i> John Wright, Investigational Drug Branch (IDB), Cancer Therapy Evaluation Program (CTEP), National Cancer Institute (NCI)
CTEP-SPONSORED EARLY-PHASE IMMUNOTHERAPY STUDIES: CLINICAL TRIAL SESSION Moderators: Elad Sharon and Howard Streicher, IDB, CTEP, NCI	
11:05 AM -11:30 AM	Keynote Lecture: Management of Immune-related Toxicities from Immune Checkpoint Inhibitors Jarushka Naidoo, Johns Hopkins
11:30 AM – 11:45 AM	Protocol # 9681: A Phase 1 Study of Cabozantinib Plus Nivolumab (CaboNivo) Alone or in Combination with Ipilimumab (CaboNivolpi) in Patients with Advanced/Metastatic Urothelial Carcinoma and Other Genitourinary Tumors Andrea Apolo, Center for Cancer Research, National Cancer Institute
11:45 AM – 12:00 PM	Protocol #S1609: DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors Sandip Patel, SWOG
12:00 PM – 12:15 PM	Protocol # 10013: Randomized Phase 2 Study of Neoadjuvant Chemotherapy, Carboplatin and Paclitaxel, with or Without Atezolizumab in Triple Negative Breast Cancer (TNBC) William Gillanders, Washington University of Saint Louis
12:15 PM – 12:30 PM	Protocol # 10026: A Phase 1 Study of Ipilimumab in Combination with Decitabine in Relapsed or Refractory Myelodysplastic Syndrome/Acute Myeloid Leukemia Jacqueline Garcia, Dana-Farber Cancer Institute
12:30 PM - 12:45 PM	BREAK
12:45 PM – 1:00 PM	PANEL DISCUSSION
CTEP PHASE I & II CLINICAL TRIALS UPDATE MODERATOR: JOHN WRIGHT, IDB, CTEP, NCI	
1:00 PM – 1:15 PM	Protocol # S1500: A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET) Sumanta “Monty” Pal, City of Hope

1:15 PM – 1:30 PM	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, National Cancer Institute. POB
1:30 PM –1:45 PM	Protocol # 10136: A Phase 2 Study of AZD1775, a Wee1 Inhibitor, in Patients with CCNE1 Amplification Siqing Fu, MD Anderson Cancer Center
1:45 PM – 2:00 PM	Protocol # 9350: A Phase I Study of Single-Agent AZD1775 (MK-1775), a Wee1 Inhibitor, in Patients with Advanced Refractory Solid Tumors Rafah Naqash, Developmental Therapeutics Clinic, National Cancer Institute
2:00 PM– 2:15 PM	BREAK
FOURTEENTH ANNUAL MICHAEL C. CHRISTIAN ONCOLOGY DRUG DEVELOPMENT AWARD & LECTURE	
2:15 PM –2:25 PM	<i>Introduction</i> John Wright, Investigational Drug Branch, CTEP, NCI
2:25 PM –2:35 PM	Presentation of Award Michael C. Christian and Jeff Moscow, IDB, CTEP, NCI
2:35 PM – 3:00 PM	AWARDEE LECTURE
3:00 PM	ADJOURN
ETCTN MEMBERS WILL MEET FROM 3:00 PM -4:00 PM DIRECTLY FOLLOWING THE CTEP EDD MEETING BY WEBINAR	

FRIDAY, OCTOBER 16, 2020

EDD Educational Workshop on Building Effective Biomarker Plans (Attendance Limited)

TIME	TOPIC	SPEAKER(S)
10:00-10:10 AM	Welcome – Goals for the Workshop	Tracy Lively Ph.D., Chief Diagnostics Evaluation Branch, NCI/DCTD
10:10-10:20 AM	Plenary Talk	Tracy Lively Ph.D., Chief Diagnostics Evaluation Branch, NCI/DCTD
10:20-10:40 AM	Topic #1: Avoiding Failure with Immunohistochemical Assays in Clinical Trials	Stephen M. Hewitt M.D., Ph.D., Head, Experimental Pathology Laboratory, NCI
10:40-11:00 AM	Topic #2: Clinical Implementation of a Pharmacodynamic Immunofluorescence Assay	Kate Ferry-Galow Ph.D. (Principal Scientist) and Ralph E Parchment Ph.D. (Senior Director), Clinical Pharmacodynamic Biomarkers Program, NCI/DCTD
11:00-11:20 AM	Topic #3: Challenges for Genomic Analysis in Trials Involving Archival Tumor Specimens	Chris Karlovich Ph.D., Associate Director, Molecular Characterization Laboratory, NCI/DCTD
11:20-11:40 AM	Topic #4: Incorporating NextGen Mass Spec Proteomic Assays into Clinical Trials	Amanda Paulovich M.D., Ph.D., Professor, Aven Foundation Endowed Chair, & Director, CLIA Targeted Proteomic Laboratory, Fred Hutchinson Cancer Research Center
11:40-11:45 AM	Break	

11:45 AM - 12:15 PM	“Challenge Scenario” / Group Discussion	Tracy Lively Ph.D., Chief Diagnostics Evaluation Branch, NCI/DCTD and Attendees
12:15-12:30 PM	Thank you and Wrap Up	Jeff Moscow, M.D., Chief, Investigational Drug Branch, NCI/DCTD