**2024 CTEP Early Drug Development Meeting**

**September 26 and 27, 2024**

**DRAFT Meeting Agenda**

**Thursday, September 26, 2024**

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| 9:00 – 9:05AM | Welcome/Introductions   **Rabih Said, Investigational Drug Branch (IDB), Cancer Therapy Evaluation Program (CTEP), National Cancer Institute (NCI)** |
| 9:05-9:35 am | **In Memoriam: Michelle A. Rudek Tribute** (Percy Ivy, Sharyn Baker, Jan Beumer, and Michael Carducci) |
| **CTEP-Sponsored Early-Phase Immunotherapy Studies: Clinical Trial Session****Moderators: Helen Chen and Cheryl Pickett-Gies, IDB, CTEP, NCI** |
| 9:35 AM – 9:55 AM | Protocol 10166: A Phase 2 Study of Atezolizumab and Cobimetinib in PD-1/PD-L1 Inhibitor Resistant or Refractory Non-Small Cell Lung Cancer (Stephen Liu, Georgetown University) |
| 9:55 AM – 10:15 AM | Protocol 10061: A Phase 1 Study of Pembrolizumab (MK-3475) in Combination with Recombinant Interleukin-12 in Patients with Solid Tumors (Diwakar Davar, University of Pittsburgh) |
| 10:15 AM – 10:35 AM | Protocol 10334: Blockade of PD-1 Added to Standard Therapy to Target Measurable Residual Disease in Acute Myeloid Leukemia 2 (BLAST MRD AML-2): A Randomized Phase 2 Study of the Venetoclax, Azacitadine, and Pembrolizumab (VAP) Versus Venetoclax and Azacitadine as First Line Therapy in Older Patients with Acute Myeloid Leukemia (AML) Who Are Ineligible or Who Refuse Intensive Chemotherapy (Rory Shallis, Yale University) |
| 10:35 AM– 10:55 AM | Protocol 10346: Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-Expressing Advanced Solid Tumors (Sarah Shin, National Cancer Institute) |
| 10:55 AM– 11:15 AM | Protocol 10398: A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Chondrosarcoma and Clear Cell Sarcoma (Andre DeSouza, National Cancer Institute) |
| 11:15 AM-11:45 PM | **Panel Discussion** |
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| 11:45 AM – 1:30 PM | **LUNCH BREAK****ETCTN Meeting (Closed Session) in Room 2W908, NCI Shady Grove (12:15 pm)** |
| **RAD51 Biomarker Educational Session (UM1 Biomarker Supplement)****Moderators:  Percy Ivy and Steve Gore, IDB, CTEP, NCI** |
| 1:30 PM – 1:45 PM | Introductory talk on functional DNA repair-based assays (RAD51, ATM and pKAP1): Geoffrey Shapiro and Bose Kochupurakkal, Dana Farber Cancer Institute |
| 1:45 PM – 2:00 PM2:00 PM – 2:15 PM2:15 PM – 2:30 PM2:30 PM – 2:45 PM | RAD51 assay in PARP inhibitor-based protocols:Protocol 10250  (Brian Van Tine, Washington University) Protocol 10096  (Rana McKay, U California San Diego) ATM and pKAP1 assays in ATR inhibitor-based protocols:Protocol 9944  (Panos Konstantinopoulos, Dana Farber Cancer Institute)Protocol 10191 (Atish Choudhury, Dana Farber Cancer Institute) |
| 2:45 PM – 3:05 PM | **Panel Discussion** |
| 3:05 PM – 3:15 PM | **BREAK** |
| **Biomarker Outcomes Trial Session (CIMAC Specimen Analysis Complete)****Moderator:  Helen Chen and Percy Ivy, IDB, CTEP, NCI** |
| 3:15 PM – 3:30 PM | Protocol 9204: A Phase I/IB Study of Ipilimumab or Nivolumab in Patients with Relapsed Hematologic Malignancies After Allogeneic Hematopoietic Cell Transplantation (Livius Penter, Charite, Germany) |
| 3:30 PM – 3:45 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/Harvard Cancer Center) |
| 3:45 PM- 4:00 PM | Protocol NRG-GY021: A Phase II Randomized Trial of Olaparib Versus Olaparib Plus Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer (Sarah Adams, NRG) |
| 4:00 PM – 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 PM- 4:30 PM | **Panel Discussion and DAY 1 Wrap-up** |
| 4:30 PM | **ADJOURN DAY 1** |
| **Friday, September 27, 2024** |
| **CTEP-Sponsored Early-Phase: Targeted Clinical Trial Session****Moderator: Lorraine Pelosof and Rabih Said, IDB, CTEP, NCI** |
| 9:00 AM – 9:10 AM | Welcome/Introductions   **Rabih Said, Investigational Drug Branch (IDB), Cancer Therapy Evaluation Program (CTEP), National Cancer Institute (NCI)** |
| 9:10 AM– 9:30 AM | Protocol 10411: Phase 2 Study of Rogaratinib (BAY 1163877) in the Treatment of Patients with Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-Deficient Gastrointestinal Stromal Tumor (GIST) (Priscilla Merriam, Dana Farber Cancer Institute/Harvard Cancer Center) |
| 9:30 AM– 9:50 AM | Protocol 10483: Phase Ib Trial of Erdafitinib Combined with Enfortumab Vedotin Following Platinum and PD1/L1 Inhibitors for Metastatic Urothelial Carcinoma with FGFR2/3 Genetic Alterations (Rohit Jain, Weill Cornell Medicine) |
| 9:50 AM -10:10 AM | Protocol 10496 A Phase 2 Study of Ipatasertib in Combination with Pembrolizumab for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (Jacob Thomas, USC Norris Cancer Center) |
| 10:10 AM -10:30 AM | Protocol NRG-GY027: Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Paclitaxel and Carboplatin with Ipatasertib as Initial Therapy of Ovarian Cancer (Katherine Fuh, NRG) |
| 10:30 AM – 10:50 AM | **Panel Discussion** |
| 10:50 AM – 11:10 AM | **BREAK** |
| **Eighteenth Annual Michaele C. Christian Oncology Drug Development Award & Lecture** |
| 11:10 AM – 11:20 AM | Introduction**Steve Gore, Investigational Drug Branch, CTEP, NCI** |
| 11:20 AM-11:30 AM | Presentation of Award**Michaele C. Christian IDB, CTEP, NCI** |
| 11:30 AM – 12:00 PM | **Awardee Lecture**  |
| 12:00 PM | **Adjourn** **(ClOSED IDSC MEETING from 1:00-4:00 PM EDT)** |