National Cancer Institute
Institutional Review Board

AGENDA
May 22, 2017
1:00 – 5:00 pm
10 CRC/3-1608

1. Call to Order/ Announcements
   - Audio-recording of Meeting
   - Introduction of Guests
   - Conflict of Interest
   - Expedited Actions Report


3. Old Business

4. New Business

5. NIH Problem Form 17C0086, "An Open-label Phase 2 Study to Evaluate PT2385 for the Treatment of Von Hippel-Lindau Disease-Associated Clear Cell Renal Cell Carcinoma" - Ramaprasad Srinivasan, PI


7. NIH Problem Form 11C0125-E, "Study of the Biology and Natural History of Disease Outcomes in Patients Treated with Allogeneic Hematopoietic Stem Cell Transplantation for Hematologic Malignancies" - Ronald Gress, PI

8. NIH Problem Form 16C0135-B, "A Pilot Study of Combined Immune Checkpoint Inhibition in Combination with Ablative Therapies in Subjects with Hepatocellular Carcinoma (HCC) or Biliary Tract Carcinomas (BTC)" - Tim Greten, PI

9. NIH Problem Form 07C0107-P, "A Randomized Phase II Trial Combining Vaccine Therapy with PROSTVAC/TRICOM and Flutamide, vs. Flutamide Alone in Men with Androgen Insensitive, Non Metastatic (D0.5) Prostate Cancer" - Ravi Madan, PI

10. NIH Problem Form 16C0145, "Phase II Trial with Safety Run-in of the Anti-Mesothelin Antibody Drug Conjugate Anetumab Ravtansine for Mesothelin Expressing Lung Adenocarcinoma" - Raffit Hassan, PI

11. NIH Problem Form 16C0099-C, "An Open Label Phase Ib Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity and Maximum Tolerated Dose of Anetumab Ravtansine in Combination with Pemetrexed 500 mg/m2 and Cisplatin 75 mg/m2 in Subjects with Mesothelin-expressing Predominantly Epithelial Mesothelioma or Non-squamous Non-small-cell Lung Cancer (BAY94-9343/17631)" - Raffit Hassan, PI

12. Continuing Review 03C0278-N, "A Comparative Study of Pediatric CNS Tumor Activity as Assessed by 18F-FDG PET Imaging and Proton Magnetic Resonance Spectroscopic Imaging (1H-MRSI)" - Kathy Warren, PI
13. Continuing Review 14C0198-D, "A Multicenter Study of Ibrutinib and Lenalidomide in Combination with DA-EPOCH-R in Subjects with Relapsed or Refractory Diffuse Large B-cell Lymphoma" - Wyndham Wilson, PI


15. Continuing Review 15C0178-D, "A Phase Ib, Dose Escalation, Multiple Dose Trial with HuMax-IL8 in Patients with Metastatic or Unresectable, Locally Advanced Malignant Solid Tumors" - Marijo Bilusic, PI


18. Continuing Review 14C0021-D, "Randomized Control Trial of Adrenalec-tomy versus Observation for Subclinical Hypercortisolism " - Dhaval Patel, PI


20. Continuing Review 16C0145, "Phase II Trial with Safety Run-in of the Anti-Mesothelin Antibody Drug Conjugate Anetumab Ravtansine for Mesothelin Expressing Lung Adenocarcinoma " - Raffit Hassan, PI

21. Continuing Review 09C0082-BB, "Assessment of the Safety and Feasibility of Administering T cells Expressing an anti-CD19 Chimeric Antigen Receptor to Patients with B-cell Lymphoma" - Steve Rosenberg, PI

22. Continuing Review 07C0189-K, "Phase I/II Trial of Vandetanib (ZD6474, ZACTIMA) in Children and Adolescents with Hereditary Medullary Thyroid Carcinoma" - Brigitte Widemann, PI

23. Continuing Review 15C0029-K, "Phase I Dose Escalation Study of Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults with Recurrent or Refractory CD22-expressing B Cell Malignancies" - Terry Fry, PI

24. Continuing Review 04C0281-AA, "Natural History Study of Clinical and Biological Factors Determining Outcomes in Chronic Graft-Versus-Host Disease" - Steven Pavletic, PI
25. **Continuing Review** 07C0107-P, "A Randomized Phase II Trial Combining Vaccine Therapy with PROSTVAC/TRICOM and Flutamide, vs. Flutamide Alone in Men with Androgen Insensitive, Non-Metastatic (D0.5) Prostate Cancer" - Ravi Madan, PI

26. **Continuing Review** 13C0132-I, "Allogeneic Hematopoietic Stem Cell Transplant for Patients with Mutations in GATA2 or the MonoMAC Syndrome" - Dennis Hickstein, PI

27. **Continuing Review** 14C0001-F, "Phase II Study of Axitinib (AG-013736) with Evaluation of the VEGF-pathway in Metastatic, Recurrent or Primary Unresectable Pheochromocytoma/Paraganglioma" - Andrea Apolo, PI

28. **Continuing Review** 06C0150-J, "A Phase II Clinical Trial of Anti-Tac(Fv)-PE38 (LMB-2) Immunotoxin for CD25 Positive Hairy Cell Leukemia" - Robert Kreitman, PI

29. **Continuing Review** 01C0030-Q, "Short-Course EPOCH - Rituximab in Untreated CD-20+ HIV-Associated Lymphomas" - Wyndham Wilson, PI

30. **Response to Stips** 15C0029-K, "Phase I Dose Escalation Study of Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults with Recurrent or Refractory CD22-expressing B Cell Malignancies" - Terry Fry, PI

31. **Response to Stips** 16C0135-B, "A Pilot Study of Combined Immune Checkpoint Inhibition in Combination with Ablative Therapies in Subjects with Hepatocellular Carcinoma (HCC) or Biliary Tract Carcinomas (BTC)" - Tim Greten, PI

32. **Response to Stips** 11C0034-H, "DICER1-Related Pleuropulmonary Blastoma Cancer Predisposition Syndrome: A Natural History Study" - Douglas Stewart, PI
33. Response to Stips
P173022, "Exploring Outcomes and Risk in Patients with Ependymoma" - Terri Armstrong, PI

34. Response to Stips
P162629, "Phase I/II Study Administering Peripheral Blood Lymphocytes Transduced with a Murine T-Cell Receptor Recognizing the G12V Variant of Mutated RAS in HLA-A*1101 Patients" - Jim Yang, PI

35. Amendment
89C0086-FF, "Clinical Manifestations and Molecular Bases of Heritable Urologic Malignant Disorders" - William Linehan, PI

36. Amendment
02C0179-AA, "Biospecimen Acquisition from Human Subjects" - James Gulley, PI

37. Amendment
16C0025-C, "A Phase 1 Study of bb2121 in BCMA-expressing Multiple Myeloma" - Jim Kochenderfer, PI

38. Amendment
09C0053-H, "Autologous and Related Allogeneic Hematopoietic Stem Cell Transplant and Cellular Therapies Data Submission to the Center for International Blood and Marrow Transplant Research (CIBMTR) and the National Marrow Donor Program (NMDP)" - Ronald Gress, PI

39. Initial Review
P173081, "A Phase 2 Single-arm Study to Evaluate Safety and Efficacy of CRS-207 with Pembrolizumab in Adults with Previously-Treated Malignant Pleural Mesothelioma" - Raffit Hassan, PI

40. Initial Review