National Cancer Institute
Institutional Review Board

AGENDA
February 5, 2018
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

2. Review of Draft Minutes, January 8, 2018

3. Old Business

4. New Business

5. NIH Problem Form
   10C0114-T, "A Phase II Study of Bevacizumab and Erlotinib in Subjects with Advanced Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC) or Sporadic Papillary Renal Cell Cancer" - Ramaprasad Srinivasan, MD, PI

6. NIH Problem Form
   17C0034-A, "A randomized, double blind phase II trial of Radiation Therapy plus Temozolomide and Pembrolizumab with and without HSPPC-96 in newly diagnosed Glioblastoma (GBM)" - Mark Gilbert, PI

7. NIH Problem Form
   13C0132-K, "Allogeneic Hematopoietic Stem Cell Transplant for Patients with Mutations in GATA2 or the MonoMAC syndrome" - Dennis Hickstein, PI

8. NIH Problem Form
   15C0075-D, "A Randomized, Placebo-Controlled Phase II Study of Multi-Epitope TARP Peptide Autologous Dendritic Cell Vaccination in Men with Stage D0 Prostate Cancer" - Hoyoung Maeng, M.D., PI

9. NIH Problem Form
   17C0066-B, "A Pilot Study to Investigate the Safety and Clinical Activity of Avelumab (MSB0010718C) in Thymoma and Thymic Carcinoma after Progression on Platinum-Based Chemotherapy" - Arun Rajan, PI

10. NIH Problem Form
    16C0003-H, "Pilot Trial of Allogeneic Blood or Marrow Transplantation for Primary Immunodeficiencies" - Jen Kanakry, PI

11. NIH Problem Form
    11C0161, "A Phase I/II Study of the Mitogen Activated Protein Kinase Kinase (MEK) 1 Inhibitor Selumetinib (AZD6244; Hydrogen Sulfate in Children with Neurofibromatosis Type 1 (NF1) and Inoperable Plexiform Neurofibromas (PN)" - Brigitte Widemann, PI

12. NIH Problem Form
    11C0113-S, "A Pilot Study of Genetically Engineered NY-ESO-1 Specific (c259) T cells in HLA-A2+ Patients with Synovial Sarcoma" - John Glod, PI

13. Continuing Review
    13C0006-C, "Phase II Trial Evaluating the Safety and Efficacy of Ruxolitinib in Patients with Smoldering and Chronic Adult T-cell Leukemia (ATL)" - Kevin Conlon, PI
14. Continuing Review 13C0202-E, "Tissue Procurement and Natural History Study of Patients with Malignant Mesothelioma and Other Mesothelin Expressing Cancers" - Raffit Hassan, PI

15. Continuing Review 14C0131-D, "A Phase II, Open-label Study in Patients with BRAF V600E-Mutated Rare Cancers with Several Histologies to Investigate the Clinical Efficacy and Safety of the Combination Therapy of Dabrafenib and Trametinib" - Robert Kreitman, PI

16. Continuing Review 16C0025-D, "A Phase 1 Study of bb2121 in BCMA-expressing Multiple Myeloma" - Jim Kochenderfer, PI

17. Continuing Review 16C0091-A, "Long-term Follow-up of Subjects Treated with bb2121" - Jim Kochenderfer, PI

18. Continuing Review 16C0099-F, "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 Nonsquamous Non-small-cell Lung Cancer (BAY94-9343/17631)" - Raffit Hassan, PI


20. Continuing Review 78C0039-AA, "Clinical, Laboratory, and Epidemiologic Characterization of Individuals and Families at High Risk of Cancer" - Margaret Tucker, M.D., PI


29. Continuing Review 16C0094-D, "A Phase 1/2 study of baricitinib, a JAK1/2 inhibitor, in chronic graft-versus-host disease (cGVHD) after allogeneic hematopoietic stem cell transplantation (SCT)" - Steven Pavletic, PI


31. Continuing Review 16C0154, "A Phase I Trial of T Cell Receptor Gene Therapy Targeting HPV-16 E7 with or without PD-1 Blockade for HPV-Associated Cancers" - Christian Hinrichs, PI

32. Continuing Review 17C0066-B, "A Pilot Study to Investigate the Safety and Clinical Activity of Avelumab (MSB0010718C) in Thymoma and Thymic Carcinoma after Progression on Platinum-Based Chemotherapy" - Arun Rajan, PI

33. Continuing Review 17C0092-B, "A Phase I/II Study of Pexa-Vec Oncolytic Virus in Combination with Immune Checkpoint Inhibition in Refractory Colorectal Cancer" - Tim Greten, PI

34. Continuing Review 09C0065-G, "Phase 1 Trial of Siplizumab and Dose-Adjusted EPOCH-Rituximab (DA-EPOCH-R) in T and NK-cell Lymphomas" - Wyndham Wilson, PI

35. Continuing Review 17C0177-A, "A Phase II Trial to Evaluate the Ability of a Dendritic Cell Vaccine to Immunize Melanoma or Epithelial Cancer Patients Against Defined Mutated Neoantigens Expressed by the Autologous Cancer" - Steve Rosenberg, PI

36. Response to Stips 02C0210-R, "Clinical, Laboratory, and Epidemiologic Characterization of Individuals and Families at High Risk of Blood and Lymph Node Malignancy" - Neil E Caporaso, MD, PI
37. Response to Stips
P173276, "A Phase IB/II Single-arm Study of M7824 (MSB0011359C) in Combination with Gemcitabine in Adults with Previously Treated Advanced Adenocarcinoma of the Pancreas" - Udo Rudloff, PI

38. Response to Stips
P173315, "A Phase I Study of the Mesothelin-Targeted Immunotoxin LMB-100 in Combination with SEL-110 in Subjects with Malignant Mesothelioma" - Raffit Hassan, PI

39. Response to Stips
P152261, "A Phase I, open-label, multiple-ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity of MSB0011359C in subjects with metastatic or locally advanced solid tumors with expansion to selected indications" - James L Gulley, MD PhD, PI

40. Response to Stips
P152467, "Docetaxel and PROSTVAC for Metastatic Castration Sensitive Prostate Cancer" - Ravi Madan, PI

41. Response to Stips
P173180, "A Pilot Study to Evaluate the Effects of Castration on the Pharmacokinetics of Zolpidem After Single Dose Administration In Men with Prostate Cancer Undergoing Androgen Deprivation Therapy Compared to Normal Healthy Females" - William Figg, PI

42. Response to Stips
P162997, "Phase 1 Dose Escalation Study of CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults with Recurrent or Refractory CD19/CD22-expressing B Cell Malignancies" - Nirali Shah, MD, PI

43. Amendment
15C0195-A, "Development and Validation of Patient Reported Outcome (PRO) Measures for Individuals with Neurofibromatosis 1 (NF1) and Plexiform Neurofibromas (PNs)" - Pamela Wolters, PI

44. Amendment
98C0037-L, "Treatment of Children with Cancer" - Brigitte Widemann, PI

45. Amendment
11C0255-M, "Clinical, Epidemiologic, and Genetic Studies of Li-Fraumeni Syndrome" - Maria Isabel Achatz, PI

46. Amendment
16C0128-F, "A Phase I/II Study of Mesothelin-Targeted Immunotoxin LMB-100 Alone or in Combination with Nab-Paclitaxel in Participants with Previously Treated Metastatic and/ or Locally Advanced Pancreatic Ductal Adenocarcinoma and Mesothelin Expressing Solid Tumors" - Christine Alewine, PI

47. Amendment
17C0027-A, "Long-Term Follow up of Patients Undergoing Hematopoietic Stem Cell Transplantation" - Steven Pavletic, PI
48. Amendment 17C0023-A, "A Phase 1/2 Trial of CV301 in Combination with Nivolumab versus Nivolumab in Subjects with Previously Treated Non-Small Cell Lung Cancer" - James L Gulley, MD PhD, PI

49. Amendment 03C0277-GG, "Cell Harvest and Preparation for Surgery Branch Adoptive Cell Therapy Protocols" - Steve Rosenberg, PI

50. Amendment 17C0038-A, "A Phase Ib Open Label, Dose Finding Trial to Evaluate the Safety, Tolerability, and Pharmacokinetics of Avelumab in Combination with M9241 (NHS-IL12) in Subjects with Locally Advanced, Unresectable, or Metastatic Solid Tumors" - James L Gulley, MD PhD, PI

51. Initial Review P173426, "BGJ398 for the Treatment of Tumor-Induced Osteomalacia" - Rachel Gafni, PI

52. Initial Review P173303, "A Phase I/II Trial to Evaluate the Safety and Immunogenicity of a messenger RNA (mRNA)-based, Personalized Cancer Vaccine Against Neoantigens Expressed by the Autologous Cancer" - Steve Rosenberg, PI

53. Initial Review P173162, "Treatment of Patients with Castration Resistant Prostate Cancer using a Multi-Targeted Recombinant Ad5 PSA/MUC1/Brachyury Based Immunotherapy Vaccines" - Marijo Bilusic, PI

54. Initial Review P162920, "Phase II clinical trial of sunitinib in sarcomas of the central nervous system" - Deric Park, PI