Adult CIRB - Late Phase Emphasis Meeting Agenda

May 7, 2020

I Continuing Review

A071801, Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared with Fractionated SRS (FSRS) for Resected Metastatic Brain Disease (Protocol Version Date 02/07/20)

II Continuing Review

A081105, Randomized Study of Erlotinib Vs Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC) (Protocol Version Date 02/26/20)

III Continuing Review

E3A06, Randomized Phase III Trial of Lenalidomide versus Observation Alone In Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma (Protocol Version Date 09/26/19)

IV Continuing Review

EA2182, A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE) (Protocol Version Date 01/08/20)

V Continuing Review

EA5142, Adjuvant Nivolumab in Resected Lung Cancers (ANVIL)-A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers (Protocol Version Date 01/23/19)
VI Continuing Review

NRG-GY018, A Phase III Randomized, Placebo-Controlled Study of Pembrolizumab (MK-3475, NSC #776864) in Addition to Paclitaxel and Carboplatin for Measurable Stage III or IVA, Stage IVB or Recurrent Endometrial Cancer (Protocol Version Date 02/27/20)

VII Continuing Review

RTOG-0724, Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy (Protocol Version Date 08/21/14)

VIII Continuing Review

RTOG-0815, A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer (Protocol Version Date 02/20/19)

IX Continuing Review

RTOG-1112, Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma (Protocol Version Date 03/25/20)

X Continuing Review

S1400, A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-Map) (Protocol Version Date 01/08/18)

XI New Study - Initial Review

A031902, CASPAR - A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer (Protocol Version Date 03/24/20)

XII New Study - Initial Review
**XIII New Study - Initial Review**

**EA8191**, Phase III Study of PET-Directed Local or Systemic Therapy Intensification in Prostate Cancer Patients with Post-Prostatectomy Biochemical Recurrence (Protocol Version Date 04/03/20)

**XIV Amendment**

**A041703**, A Phase II Study of Inotuzumab Ozogamicin Followed by Blinatumomab for Ph-Negative CD22-Positive B-Lineage Acute Lymphoblastic Leukemia in Newly Diagnosed Older Adults or Adults with Relapsed or Refractory Disease (Protocol Version Date 02/26/20)

**XV Amendment**

**A051701**, Randomized Phase II/III Study of Venetoclax (ABT 199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double-Expressing Lymphomas (Protocol Version Date 03/10/20)

**XVI Amendment**

**EA6141**, Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma (Protocol Version Date 03/04/20)

**XVII Amendment**

**NRG-GI004**, Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIt) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer (Protocol Version Date 03/30/20)
XVIII Amendment

RTOG-1216, Randomized Phase II/III Trial of Adjuvant Radiation Therapy with Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in Pathologic High-Risk, HPV-Negative Head and Neck Cancer (Protocol Version Date 03/20/20)