

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



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EA8183, A Phase III Double Blinded Study of Early Intervention after RADICAL ProstaTEctomy with Androgen Deprivation Therapy with or without Darolutamide vs Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE) (Protocol Version Date 03/25/20)

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)
