

Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, December 7, 2017 9:00 am – 12:50 pm (Eastern)

I. Initial Review

EA3163, Phase II Randomized Trial of Neo-Adjuvant Chemotherapy followed by Surgery and Post-Operative Radiation versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC) (Protocol Version Date 10/18/17)

II. Initial Review

NRG-GU006, A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radiotherapy with or without Enhanced Anti-Androgen Therapy with Apalutamide in Recurrent Prostate Cancer (Protocol Version Date 10/26/17)

III. Initial Review

EA9152, A Phase Ib/II Study of Venetoclax (ABT-199) in Combination with Liposomal Vincristine in Patients with Relapsed or Refractory T-cell or B-cell Acute Lymphoblastic Leukemia (Protocol Version Date 11/06/17)

IV. Amendment Review (Addendum 11)

E1A11, Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE) (Protocol Version Date 10/17/17)

V. Continuing Review

A091105, A Phase III, Double Blind, Randomized, Placebo-Controlled Trial of Sorafenib in Desmoid Tumors or Aggressive Fibromatosis (DT/DF) (Protocol Version Date 03/22/17)

VI. Continuing Review

RTOG-0924, Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial (Protocol Version Date 10/31/17)

VII. Continuing Review

RTOG-1216, Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin versus Docetaxel versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of the Head and Neck (Protocol Version Date 11/09/15)

VIII. Continuing Review

S1404, A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma (Protocol Version Date 11/08/17)

IX. Continuing Review

NSABP-B-49, A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer (Protocol Version Date 04/16/14)