

Adult CIRB - Late Phase Emphasis Meeting Agenda

October 1, 2020

I Continuing Review ReReview

A031801, A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RADICAL) (Protocol Version Date 06/08/20)

II Continuing Review

EA3163, Phase II Randomized Trial of Neoadjuvant 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 02/26/20)

III Continuing 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 06/22/20)

IV Continuing Review

GOG-0262, A Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #113912) in the Treatment of Primary Stage II, III OR IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer and ACRIN 6695: Perfusion CT Imaging To Evaluate Treatment Response in Patients Participating in GOG-0262 (Protocol Version Date 11/07/18)

V Continuing Review

NRG-GI003, A Phase III Randomized Trial of Protons versus Photons for Hepatocellular Carcinoma (Protocol Version Date 10/18/19)

VI Continuing 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 (BALANCE*) *Biomarker trial of ApaLutamide and rAdiation for recurrent prostate CancEr (Protocol Version Date 07/15/19)

VII Continuing Review

NRG-GY007, A Phase I/II Study of Ruxolitinib with Front-Line Neoadjuvant and Post-Surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Protocol Version Date 02/28/20)

VIII Continuing Review

NRG-LU002, Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial (Protocol Version Date 03/02/20)

IX Continuing Review

S1702, A Phase II Study of Isatuximab (SAR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis (Protocol Version Date 07/10/19)

X New Study - Initial Review

NRG-BN009, Phase III Trial of Salvage Stereotactic Radiosurgery (SRS) or SRS + Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for First or Second Distant Brain Relapse after Upfront SRS with Brain Metastasis Velocity ≥ 4 Brain Metastases/Year (Protocol Version Date 09/10/20)

XI Amendment

EAA173, Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) (Protocol Version Date 08/06/20)

XII Amendment

S1922, Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI In Refractory Small Bowel Adenocarcinoma (Protocol Version Date 08/20/20)

XIII Patient Recruitment Material/Information Docs

NRG-BR004, A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (Protocol Version Date 03/09/20)
