

Adult CIRB - Late Phase Emphasis Meeting Agenda

June 15, 2023

I New Study - Initial Review

A092105, Randomized Phase 2 Study of Nivolumab and Ipilimumab with or without Cabozantinib in Patients with Advanced Nasopharyngeal Carcinoma that have Progressed after Platinum Treatment and Immunotherapy (Version Date 04/24/23)

II New Study - Initial Review

NRG-GU013, The Phase III "High Five Trial" Five Fraction Radiation for High-Risk Prostate Cancer (Version Date 05/04/23)

III New Study - Initial Review

S2213, A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis (Version Date 04/10/23)

IV Continuing Review

A031801, A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RadiCaL) (Version Date 02/15/22)

V Continuing Review

A092001, Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma (Version Date 11/08/22)

VI Continuing Review

S2104, Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors (Version Date 01/24/23)

VII Continuing Review

EA1183, FDG PET to Assess Therapeutic Response in Patients with Bone-dominant Metastatic Breast Cancer, FEATURE (Version Date 10/21/22)

VIII Continuing Review

NRG-GI008, Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-US) (Version Date 02/01/22)

IX Continuing Review

E2905, Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia (Version Date 08/12/22)

X Continuing Review

NRG-BR004, A Randomized, Double-Blind, Phase III Trial of Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (Version Date 08/15/22)

XI Continuing Review

EA2183, A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA) (Version Date 02/07/23)
