

Adult CIRB - Late Phase Emphasis Meeting Agenda

November 16, 2023

I New Study - Initial Review

CCTG PR.24, Androgen Suppression Combined with Elective Nodal Irradiation and Dose Escalated Prostate Treatment: A Non-Inferiority, Phase III Randomized Controlled Trial of Stereotactic Body Radiation Therapy versus Brachytherapy Boost in Patients with Unfavourable Risk Localized Prostate Cancer (ASCENDE SBRT) (Version Date 09/29/23)

II New Study - Initial Review

NRG-GY032, A Phase II Study of Tailored Adjuvant Therapy in Pole-Mutated and p53-Wildtype/NSMP Early-Stage Endometrial Cancer (RAINBO BLUE & TAPER) (Version Date 01/16/23)

III Continuing Review

A032101, A Phase 2 Trial of ADT Interruption in Patients Responding Exceptionally to AR-Pathway Inhibitor in Metastatic Hormone-Sensitive Prostate Cancer (MHSPC): A-DREAM (Version Date 08/04/23)

IV Continuing Review

A031704, PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE] (Version Date 09/06/23)

V Continuing Review

NRG-BR002, A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer (Version Date 09/21/22)



VI Continuing Review

NRG-LU008, Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed by Concurrent Mediastinal Chemoradiation for Locally-Advanced Non-Small Cell Lung Cancer (Version Date 03/30/23)

VII Continuing Review

A022102, Randomized Phase III trial of mFOLFIRINOX +/- Nivolumab vs. FOLFOX +/- Nivolumab for First-Line Treatment of Metastatic HER2-Negative Gastroesophageal Adenocarcinoma (Version Date 09/06/23)

VIII Continuing Review

NRG-BN010, A Safety Run-In and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma (Version Date 10/19/23)

IX Continuing Review

S2302, Pragmatica - Lung: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) plus Pembrolizumab (MK-3475; NSC 776864) versus Standard of Care (SOC) for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Version Date 09/28/23)