

Adult CIRB - Late Phase Emphasis Meeting Agenda

June 20, 2024

I New Study - Initial Review

NRG-BN013, Phase III Trial of Single Fraction Stereotactic Radiosurgery (SRS) versus Fractionated SRS (FSRS) for Intact Brain Metastases (Version Date 05/15/24)

II New Study - Initial Review

NRG-BN014, A Phase III Randomized Clinical Trial of Proton Craniospinal Irradiation versus Involved-Field Radiotherapy for Patients with Breast Cancer or Non-Small Cell Lung Cancer Leptomeningeal Metastasis (RADIATE-LM) (Version Date 05/20/24)

III Amendment

S2302, Pragmatica - Lung: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) plus Pembrolizumab (MK-3475; NSC 776864) versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Version Date 03/01/24)

IV Amendment Prior to Activation

A072201, Randomized Phase II Trial of Anti-Lag-3 and Anti-PD-1 Blockade vs. SOC in Patients with Recurrent Glioblastoma (Version Date 06/06/24)

V Continuing Review

A031803, Phase II Trial of Intravesical Gemcitabine and MK-3475 (pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (Version Date 03/21/23)

VI Continuing 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 10/26/23)

VII Continuing Review

ABTC-1604, Phase 0/I Study of AMG 232 (KRT 232) Concentrations in Brain Tissue in Patients with Recurrent Glioblastoma and of AMG 232 (KRT 232) in Combination with Radiation in Patients with Newly Diagnosed Glioblastoma and Unmethylated MGMT Promoters (Version Date 01/19/24)

VIII Continuing Review

CALGB-100104, A Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC #703813, IND#70116) or Placebo Following Autologous Stem Cell Transplantation for Multiple Myeloma (Version Date 09/27/19)

IX Continuing Review

CCTG MA.39, Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer (Version Date 09/19/22)

X Continuing Review

NRG-GI006, Phase III Randomized Trial of Proton Beam Therapy (PBT) versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer (Version Date 11/05/20)

XI Continuing Review

NRG-GU013, The Phase III "High Five Trial" Five Fraction Radiation for High-Risk Prostate Cancer (Version Date 07/07/23)

XII Continuing Review

S1806, Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer (Version Date 01/09/24)

XIII Continuing Review

S2007, A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases (Version Date 10/10/22)

XIV Continuing Review

S2209, A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or in a Subset of "Intermediate Fit" Comparing Upfront Three-Drug Induction Regimens Followed by Double- or Single-Agent Maintenance (Version Date 02/22/24)
