

Adult CIRB - Late Phase Emphasis Meeting Agenda

November 7, 2024

I New Study - Initial Review

EA4231, A Phase II Study of Venetoclax, Ibrutinib, Prednisone, Obinutuzumab, and Revlimid (ViPOR) in Relapsed or Refractory CD10-Negative Diffuse-Large B-Cell Lymphoma (DLBCL) and High-Grade B-Cell Lymphoma with MYC and BCL2 rearrangements (HGBCL-DH-BCL2) (Version Date 09/16/24)

II New Study - Initial Review

MM10A-S03, Randomized Phase II Trial of Oral Decitabine and Cedazuridine and Venetoclax Compared with Oral Decitabine and Cedazuridine, Venetoclax, and Enasidenib for Newly Diagnosed Older Adults with IDH2 Mutant Acute Myeloid Leukemia: A MyeloMATCH Treatment Trial (Version Date 09/30/24)

III Amendment

S1827, MRI Brain Surveillance Alone versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK) (Version Date 09/17/24)

IV 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)

V Continuing Review

EA5221, A Randomized Phase III Trial of Chemo Immunotherapy vs Immunotherapy Alone for the Vulnerable Older Adult with Advanced Non-Small Cell Lung Cancer: The ACHIEVE Study (Version Date 05/16/24)

VI 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 10/03/23)

VII 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)

VIII 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 05/28/24)

IX 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 03/11/24)

X 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 10/04/24)
