

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 5, 2021

I Continuing Review

A041702, A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib plus Venetoclax and Obinutuzumab in Untreated Older Patients (≥ 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 04/09/21)

II Continuing Review

A091605, A Randomized Phase II Study of anti-PD1 antibody [pembrolizumab (MK-3475)] alone versus anti- PD1 antibody plus Stereotactic Body Radiation therapy in advanced Merkel Cell Carcinoma (Protocol Version Date 08/07/20)

III Continuing Review

EA9161, A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 12/30/20)

IV 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 (Protocol Version Date 06/28/21)

V Continuing Review

RTOG-0924, Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial (Protocol Version Date 12/13/18)

VI Continuing Review

S1801, A Phase II Randomized Study of Adjuvant versus Neoadjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High Risk Melanoma (Protocol Version Date 04/26/21)

VII New Study ReReview

A032002, Phase II Randomized Trial of Atezolizumab versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART) (Protocol Version Date 07/23/21)

VIII New Study - Initial Review

NRG-GU010, Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE) (Protocol Version Date 07/14/21)

IX New Study - Initial Review

S1934, NASSIST (Neoadjuvant Chemoradiation +/- Immunotherapy Before Surgery for Superior Sulcus Tumors): A Randomized Phase II Trial of Trimodality +/- Atezolizumab in Resectable Superior Sulcus Non-Small Cell Lung Cancer (Protocol Version Date 07/01/21)
