

**Adult CIRB - Late Phase Emphasis Meeting Agenda**

**September 3, 2020**

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**I Continuing Review**

**A041702**, A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib plus Venetoclax and Obinutuzumab in Untreated Older Patients ( $\geq 70$  Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 06/26/20)

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**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)

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**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 07/02/20)

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**IV Continuing Review**

**NRG-BR004**, A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (Protocol Version Date 03/09/20)

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**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)

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**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 02/19/20)

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**VII New Study - Initial Review**

**AMC-107**, A Phase 2 Trial of Ixazomib for Kaposi Sarcoma (Protocol Version Date 07/24/20)

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**VIII New Study - Initial Review**

**EA9181**, A Phase III Randomized Trial of Steroids +Tyrosine Kinase Inhibitor Induction with Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-positive Acute Lymphoblastic Leukemia in Adults (Protocol Version Date 08/06/20)

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**IX Amendment**

**A051701**, Randomized Phase II/III Study of Venetoclax (ABT 199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double-Expressing Lymphomas (Protocol Version Date 08/03/20)

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**X Memos**

**NRG-BR004**, A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (Protocol Version Date 03/09/20)

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