Adult CIRB - Late Phase Emphasis Meeting Agenda

September 3, 2020

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 06/26/20)

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 07/02/20)

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)

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 02/19/20)

VII New Study - Initial Review

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

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)

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)

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)