

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

**December 3, 2020**

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**I 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] (Protocol Version Date 10/29/20)

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**II Continuing Review**

**A041501**, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Protocol Version Date 09/04/20)

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**III Continuing Review**

**EA5163**, INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis (Protocol Version Date 05/04/20)

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**IV Continuing Review**

**EA6183**, A Phase II Neoadjuvant Study of Encorafenib with Binimetinib in Patients with Resectable Locoregional Metastases from Cutaneous or Unknown Primary Melanoma (Stages III N1B/C/D) (Protocol Version Date 08/11/20)

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**V Continuing Review**



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**EA8171**, Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer (Protocol Version Date 03/30/20)

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## **VI Continuing Review**

**EA9171**, BLAST MRD CML 1 Trial: BLockade of PD-1 Added to Standard Therapy to Target Measurable Residual Disease (MRD) in Chronic Myeloid Leukemia (CML)- A Phase II Study of Adding the Anti-PD-1 Pembrolizumab to Tyrosine Kinase Inhibitors in Patients with CML and Persistently Detectable MRD (Protocol Version Date 06/08/20)

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## **VII Continuing Review**

**NRG-LU006**, Phase III Randomized Trial of Pleurectomy/Decortication Plus Chemotherapy with or without Adjuvant Hemithoracic Intensity-Modulated Pleural Radiation Therapy (IMPRINT) for Malignant Pleural Mesothelioma (MPM) (Protocol Version Date 01/02/20)

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## **VIII Continuing Review**

**S1416**, Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer with or Without Brain Metastases (Protocol Version Date 08/20/20)

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## **IX Continuing Review**

**S1914**, A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC (Protocol Version Date 04/13/20)

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