

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

**January 2, 2020**

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**I Continuing Review ReReview**

**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 10/09/19)

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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 06/29/18)

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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 04/17/19)

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**IV Continuing Review**

**EA8171**, Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer (Protocol Version Date 11/14/19)

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**V Continuing Review**

**EA9171**, Phase II Study of Adding the Anti-PD-1 Pembrolizumab to Tyrosine Kinase Inhibitors in Patients with Chronic Myeloid Leukemia and Persistently Detectable Minimal Residual Disease (Protocol Version Date 11/27/19)

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**VI 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 08/14/19)

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**VII New Study - Initial Review**

**EA8185**, Phase 2 Study of Bladder-Sparing Chemoradiation with MEDI4736 (Durvalumab) in clinical Stage 3, Node Positive bladder cancer (INSPIRE) (Protocol Version Date 12/05/19)

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**VIII New Study - Initial Review**

**NRG-GY020**, A Phase III Randomized Trial of Radiation +/- MK-3475 (Pembrolizumab) for Newly Diagnosed, High Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer (Protocol Version Date 11/19/19)

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**IX New Study - Initial 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 12/05/19)

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**X Amendment**

**NRG-GY006**, A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer (Protocol Version Date 11/25/19)

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