

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

**February 18, 2021**

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**I Continuing Review**

**A041202**, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients ( $\geq$  65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 03/20/19)

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**II Continuing Review**

**EA8143**, A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC) (Protocol Version Date 09/02/20)

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**III Continuing Review**

**EAF151**, Change in Relative Cerebral Blood Volume as a Biomarker for Early Response to Bevacizumab in Patients with Recurrent Glioblastoma (Protocol Version Date 05/08/20)

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**IV Continuing Review**

**NRG-BR002**, A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer (Protocol Version Date 07/11/18)

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**V Continuing Review**

**NRG-GY012**, A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer (Protocol Version Date 06/11/19)

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## **VI Continuing Review**

**S1403**, A Randomized Phase II Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC) (BI 1200.124) (Protocol Version Date 07/29/20)

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## **VII Continuing Review**

**S1929**, Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) (Protocol Version Date 12/04/20)

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## **VIII Continuing Review**

**S1933**, A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status (Protocol Version Date 10/15/20)

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## **IX New Study - Initial Review**

**EA2192**, APOLLO: A Randomized Phase II Double-Blind Study of Olaparib versus Placebo Following Adjuvant Chemotherapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation (Protocol Version Date 01/08/21)

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## **X New Study - Initial Review**

**EA2201**, A Phase II Study of Neoadjuvant Nivolumab plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma (Protocol Version Date 12/29/20)

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## **XI New Study - Initial Review**

**NRG-GY023**, A Randomized Phase II Trial of Triplet Therapy (A PD-L1 Inhibitor MEDI4736 (Durvalumab) in Combination with Olaparib and Cediranib) Compared to Olaparib and Cediranib or MEDI4736 (Durvalumab) and Cediranib or Standard of Care Chemotherapy in



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Women with Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer who have Received Prior Bevacizumab (Protocol Version Date 11/17/20)

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