

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

**May 18, 2023**

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**I New Study - Initial Review**

**A052101**, A Randomized Phase 3 Trial of Continuous vs Intermittent Maintenance Therapy with Zanubrutinib as Upfront Treatment in Older Patients with Mantle Cell Lymphoma (Version Date 04/05/23)

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**II Amendment Prior to Activation**

**MM1YA-S01**, A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) vs (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax and Azacitidine + Venetoclax in Patients Aged 59 or Younger Who Are Considered High Risk (Adverse) Acute Myeloid Leukemia as Determined by MyeloMATCH; A MyeloMATCH Clinical Trial (Version Date 03/10/23)

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**III Continuing Review**

**A032002**, Phase II Randomized Trial of Atezolizumab versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART) (Version Date 06/21/22)

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**IV Continuing Review**

**EA2197**, Optimal Perioperative Therapy For Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial (Version Date 03/03/22)

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**V Continuing Review**

**NRG-HN010**, A Controlled, Randomized Phase II Trial of Docetaxel Plus Trastuzumab Versus Ado-Trastuzumab Emtansine for Recurrent, Metastatic, or

Treatment-Naïve, Unresectable HER2-Positive Salivary Gland Cancer (Version Date 06/21/22)

**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 (Version Date 02/15/23)

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**VII Continuing Review**

**S2200**, A Phase II Randomized Trial of Cabozantinib (NSC #761968) with or without Atezolizumab (NSC #783608) in Patients with Advanced Papillary Renal Cell Carcinoma (PAPMET2) (Version Date 11/11/22)

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**VIII Continuing Review**

**EA5181**, Randomized Phase III Trial of MEDI4736 (durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (Version Date 06/07/22)

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