

## **Adult CIRB - Early Phase Emphasis Meeting Agenda**

**November 21, 2023**

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### **I New Study - Initial Review**

**EAY191-N5**, A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination with Palbociclib, a CDK4/6 Inhibitor, in Patients with HER2+ Gynecologic Cancers and Other Solid Tumors: A ComboMATCH Treatment Trial (Version Date 10/19/23)

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### **II Amendment**

**10287**, A randomized Phase I/II trial of fulvestrant and abemaciclib in combination with copanlisib (FAC) versus fulvestrant and abemaciclib alone (FA) for endocrine-resistant, hormone receptor positive, HER2 negative metastatic breast cancer (FAC vs FA) (Version Date 09/29/23)

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### **III Amendment**

**NRG-LU004**, Phase I Trial of Radiotherapy Combined With Durvalumab Alone Plus Either Monalizumab or Oleclumab in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1) (Version Date 10/16/23)

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### **IV Continuing Review**

**10020**, A Phase II Open-Label, Randomized Study of PARP Inhibition (olaparib) Either Alone or in Combination with Anti-PD-L1 Therapy (atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-positive Breast Cancer (Version Date 08/24/23)

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### **V Continuing Review**

**10166**, A Phase 2 Study of Atezolizumab and Cobimetinib in PD-1/PD-L1 Inhibitor Resistant or Refractory Non-Small Cell Lung Cancer (Version Date 10/09/23)

## **VI Continuing Review**

**10346**, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Version Date 10/06/23)

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## **VII Continuing Review**

**10250**, A Phase II Study of the PARP Inhibitor Olaparib in Combination with the DNA Damaging Agent Temozolomide for the Treatment of Advanced Uterine Leiomyosarcoma (Version Date 07/12/23)

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## **VIII Continuing Review**

**10440**, A Phase 1/1a Study of Venetoclax, MLN9708 (ixazomib citrate) and Dexamethasone for Relapsed/Refractory Light Chain Amyloidosis (Version Date 09/21/23)

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## **IX Continuing Review**

**10496**, A Phase 2 Study of Ipatasertib in Combination with Pembrolizumab for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (Version Date 02/23/23)

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