

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

**June 2, 2022**

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### **I Continuing Review**

**10231**, NCORP Tissue Procurement Protocol: An NCI Cancer Moonshot Study (Protocol Version Date 09/20/19)

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### **II Continuing Review**

**A041703**, A Phase II Study of Inotuzumab Ozogamicin Followed by Blinatumomab for Ph-Negative CD22-Positive B-Lineage Acute Lymphoblastic Leukemia in Newly Diagnosed Older Adults or Adults with Relapsed or Refractory Disease (Protocol Version Date 11/02/21)

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### **III Continuing Review**

**E1A11**, Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE) (Protocol Version Date 10/21/20)

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### **IV Continuing Review**

**E4412**, A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma (Protocol Version Date 06/22/21)

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### **V Continuing Review**

**EA4181**, A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients  $\leq$  70 years old with Untreated Mantle Cell Lymphoma (Protocol Version Date 03/03/22)

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### **VI Continuing Review**

**S1815**, A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers (Protocol

Version Date 06/13/21)

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## **VII New Study - Initial 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 (Protocol Version Date 05/06/22)

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