

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

**April 18, 2024**

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**I New Study - Initial Review**

**EA3231**, A Randomized Phase III Study of BRAF-Targeted Therapy vs Cabozantinib in RAI-Refractory Differentiated Thyroid Cancer with BRAF V600Em (Version Date 03/11/24)

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**II Amendment Prior to Activation**

**EA7222**, A Randomized Phase III Trial of Doxorubicin + Pembrolizumab Versus Doxorubicin Alone for the Treatment of Undifferentiated Pleomorphic Sarcoma (UPS) and Related Poorly Differentiated Sarcomas (Version Date 02/16/24)

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**III Continuing Review**

**A032002**, Phase II Randomized Trial of Immunotherapy Versus Immunotherapy and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (IMMORTAL) (Version Date 03/29/24)

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**IV Continuing Review**

**A041702**, A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib plus Venetoclax and Obinutuzumab in Untreated Older Patients ( $\geq$  65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Version Date 04/18/22)

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**V Continuing Review**

**EA2197**, Optimal Perioperative Therapy For Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial (Version Date 07/20/23)

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## **VI 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)

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## **VII Continuing Review**

**NRG-LU002**, Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial (Version Date 10/18/23)

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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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