

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

**October 15, 2020**

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**I Continuing Review**

**A041701**, A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy (Protocol Version Date 04/09/19)

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**II Continuing Review**

**A091802**, Phase II Randomized Trial of Avelumab Plus Cetuximab versus Avelumab Alone in Advanced Cutaneous Squamous Cell Carcinoma of the Skin (cSCC) (Protocol Version Date 09/16/20)

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**III Continuing Review**

**A151804**, Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events (Protocol Version Date 11/21/19)

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**IV Continuing Review**

**E1A06**, An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) Versus Melphalan, Prednisone and Lenalidomide (Revlimid TM) (MPR) in Newly Diagnosed Multiple Myeloma Patients Who Are Not Candidates for High-Dose Therapy (Protocol Version Date 06/15/16)

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**V Continuing Review**

**E4512**, A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein (Protocol Version Date 02/08/19)

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**VI Continuing Review**

**NRG-BN001**, Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma (Protocol Version Date 11/19/19)

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**VII Continuing Review**

**NRG-GU008**, Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer after Radical Prostatectomy (INNOVATE) INTensifying treatment for NOde positive prostate cancer by VARving the hormonal ThErapy (Protocol Version Date 09/18/20)

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**VIII Continuing Review**

**NRG-LU003**, A Biomarker-Driven Protocol for Previously Treated ALK-Positive Non-Squamous NSCLC Patients: The NCI-NRG ALK Protocol (Protocol Version Date 08/11/20)

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**IX New Study - Initial Review**

**AMC-108**, Multicenter Phase II Study of Pomalidomide Monotherapy in Kaposi Sarcoma (Protocol Version Date 09/09/20)

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**X New Study - Initial Review**

**S1937**, A Phase III Randomized Trial of Eribulin (NSC #707389) with or without Gemcitabine versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy (Protocol Version Date 09/15/20)

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**XI New Study - Initial Review**

**S2007**, A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016 ) for Patients with HER2-Negative Breast Cancer and Brain Metastases (Protocol Version Date 09/10/20)

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**XII Amendment**

**A031102**, A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors (Protocol Version Date 09/22/20)

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**XIII Amendment**

**A041701**, A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy (Protocol Version Date 09/11/20)

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**XIV Amendment**

**A151804**, Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events (Protocol Version Date 08/31/20)

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**XV Memos**

**EA9161**, A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 07/02/20)

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