

Adult CIRB - Late Phase Emphasis Meeting Agenda

September 2, 2021

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 09/11/20)

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)

III 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)

IV 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 07/27/21)

V Continuing Review

EAA181, Effective Quadruplet Utilization After Treatment Evaluation (EQUATE): A Randomized Phase 3 Trial for Newly Diagnosed Multiple Myeloma Not Intended for Early Autologous Transplantation (Protocol Version Date 04/05/21)

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)

VII 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)

VIII Continuing Review

S2001, Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations (Protocol Version Date 11/09/20)

IX New Study - Initial Review

NRG-HN009, Randomized Phase II/III Trial of Radiation with High-Dose Cisplatin (100 mg/m²) Every Three Weeks Versus Radiation with Low-Dose Weekly Cisplatin (40 mg/m²) for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN) (Protocol Version Date 07/26/21)

X Amendment

EA3161, A Phase II/III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPSCC (Protocol Version Date 07/28/21)

XI Amendment

S2005, A Phase II Randomized Study of Ibrutinib and Rituximab with or without Venetoclax in Previously Untreated Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL) (Protocol Version Date 07/09/21)
