

Adult CIRB - Late Phase Emphasis Meeting Agenda

November 2, 2023

I New Study - Initial Review

EAF223, Phase II Glioblastoma Accelerated Biomarkers Learning Environment Trial (GABLE) (Version Date 09/22/23)

II Continuing Review

A011202, A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy (Version Date 06/07/22)

III Continuing Review

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 (Version Date 07/23/21)

IV Continuing Review

A041202, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (\geq 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Version Date 12/21/21)

V Continuing Review

A081801, Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO) (Version Date 09/01/23)

VI Continuing Review

A091903, A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma (Version Date 08/23/23)

VII Continuing Review

A092107, A Randomized Phase 2 Trial with a Safety Lead-In to Evaluate Palbociclib versus Palbociclib and Cemiplimab for the Treatment of Advanced Dedifferentiated Liposarcoma (Version Date 06/21/23)

VIII Continuing Review

E1912, A Randomized Phase III Study of Ibrutinib (PCI- 32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Version Date 01/20/23)

IX Continuing Review

EA8134, InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study) (Version Date 05/24/21)

X Continuing Review

NRG-GY012, A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combinations of Cediranib/Olaparib, Olaparib/Durvalumab (MEDI4736), Cediranib/Durvalumab (MEDI4736), Olaparib/AZD5363 (Capiwasertib) in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. A Multi-Arm Trial for Women with Recurrent or Persistent Endometrial Cancer (Version Date 07/26/23)

XI Continuing Review

NRG-GY019, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (Version Date 05/23/23)

XII Continuing Review

NRG-GY025, A Randomized Phase II Trial of Nivolumab and Ipilimumab Compared to Nivolumab Monotherapy in Patients with Deficient Mismatch Repair System Recurrent Endometrial Carcinoma (Version Date 08/04/23)

XIII Memos

CALGB-40503, Endocrine Therapy with or without ANTI-VEGF Therapy: A Randomized, Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab (NSC 704865; IND 7921) for Women with Hormone Receptor-Positive Advanced Breast Cancer (Version Date 02/06/19)
