

Adult CIRB - Late Phase Emphasis Meeting Agenda

October 19, 2023

I New Study - Initial Review

EA5221, A Randomized Phase III Trial of Chemo Immunotherapy vs Immunotherapy Alone for the Vulnerable Older Adult with Advanced Non-Small Cell Lung Cancer: The ACHIEVE Study (Version Date 09/20/23)

II Amendment

AMC-112, Axicabtagene Ciloleucel in Relapsed or Refractory HIV-Associated Aggressive B-Cell Non-Hodgkin Lymphoma (Version Date 09/19/23)

III Continuing Review

A031702, A Phase II Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC) (Version Date 09/06/23)

IV Continuing Review

A012103, OptimICE-PCR: De-Escalation of Therapy in Early-Stage TNBC Patients who Achieve pCR after Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy (Version Date 03/23/23)

V Continuing Review

GOG-0213, A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel (Or Gemcitabine) Alone or in Combination with Bevacizumab (NSC #704865, IND #113912) followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer. NCI-Supplied Agents: Bevacizumab (NSC #704865, IND #113912) NCT# 00565851 (Version Date 11/16/18)

VI Continuing Review

A071701, Genomically-Guided Treatment Trial in Brain Metastases (Version Date 05/17/22)

VII Continuing Review

ABTC-1802, A Phase II Study of Binimetinib in Combination with Encorafenib in Adults with Recurrent BRAF V600-Mutated High-Grade Astrocytoma or other Primary Brain Tumor (Version Date 05/24/21)

VIII Continuing Review

CCTG CE.7, A Phase III Trial of Stereotactic Radiosurgery Compared with Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) Plus Memantine for 5 or More Brain Metastases (Version Date 04/01/22)

IX Continuing Review

GOG-0281, A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer. NCT # NCT02101788 (Version Date 09/19/22)

X Continuing Review

NRG-BN005, A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas (Version Date 11/21/22)

XI Continuing Review

NRG-GY028, A Phase IB and Randomized Phase II Trial of Megestrol Acetate with or without Ipatasertib in Recurrent or Metastatic Endometrioid Endometrial Cancer (Version Date 04/06/23)

XII Continuing Review

NRG-HN001, Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA) (Version Date 10/03/22)

XIII Continuing Review

NRG-LU005, Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab (Version Date 11/03/22)

XIV Continuing Review

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)
