

Adult CIRB - Late Phase Emphasis Meeting Agenda

November 3, 2022

I New Study - Initial Review

A022004, Randomized Trial of Consolidation Targeted Adjuvant Therapy with Encorafenib and Cetuximab versus Usual Care for Patients with Stage II/III BRAF V600E Colon Cancer (Version Date 09/22/22)

II New Study - Initial Review

A022102, Randomized Phase III trial of mFOLFIRINOX +/- Nivolumab vs. FOLFOX +/- Nivolumab for First-Line Treatment of Metastatic HER2-Negative Gastroesophageal Adenocarcinoma (Version Date 09/29/22)

III New Study - Initial 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 09/26/22)

IV Continuing Review

A031702, A Phase II Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC) (Version Date 02/01/21)

V Continuing Review

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

VI 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)

VII Continuing Review

E4A03, A Randomized Phase III Study of CC-5013 Plus Dexamethasone Versus CC-5013 Plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide Plus Dexamethasone Salvage Therapy for Non-Responders (Version Date 09/27/19)

VIII Continuing Review

EA3161, A Phase III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPSCC (Version Date 12/02/21)

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 10/15/21)



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XI Continuing Review

S1007, A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial RX for Positive Node, Endocrine Responsive Breast Cancer (Version Date 12/10/21)

XII Continuing Review

EA3191, A Phase II Randomized Trial of Adjuvant Therapy with Pembrolizumab after Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma with High Risk Features (Version Date 02/10/22)
