

Adult CIRB - Late Phase Emphasis Meeting Agenda

December 2, 2021

I Continuing Review

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

II Continuing Review

A071701, Genomically-Guided Treatment Trial in Brain Metastases (Protocol Version Date 08/05/20)

III 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 (Protocol Version Date 02/06/19)

IV Continuing Review

CCTG CE.7, A Phase III Trial of Stereotactic Radiosurgery Compared with Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) Plus Memantine for 5-15 Brain Metastases (Protocol Version Date 09/01/20)

V 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 (Protocol Version Date 09/27/19)

VI Continuing Review

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

VII 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 (Protocol Version Date 10/12/21)

VIII 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 (Protocol Version Date 07/24/20)

IX 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 (Protocol Version Date 10/15/21)

X 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 (Protocol Version Date 07/02/21)

XI New Study - Initial Review

S2015, Melanoma Margins Trial (MelMarT): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma (Protocol Version Date 09/01/21 US Protocol Version Date 10/14/21)
