

Adult CIRB - Late Phase Emphasis Meeting Agenda

February 6, 2020

I Continuing Review

ANZGOG-0902-GOG-0274, A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: THE OUTBACK TRIAL (ANZGOG 0902/GOG-0274/RTOG 1174) (Protocol Version Date 05/09/16)

II 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 04/11/19)

III Continuing Review

E2108, A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer (Protocol Version Date 03/10/15)

IV Continuing Review

E2906, Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age \geq 60 Years) (Protocol Version Date 05/15/17)

V Continuing Review



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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 II/III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPCA (Protocol Version Date 03/22/19)

VII 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 08/22/18)

VIII New Study - Initial Review

S1900D, A Randomized Phase II Study of TAK228 (MLN0128, SAPANISERTIB) plus Docetaxel versus Standard of Care in Patients with Previously-Treated NFE2L2 or KEAP1-Positive Stage IV or Recurrent Squamous Cell Lung Cancer (ECOG-ACRIN LUNG-MAP SUB-STUDY) (Protocol Version Date 12/18/19)

IX Amendment

S1815, A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers (Protocol Version Date 11/25/19)

X Patient Recruitment Material/Information Docs

EA8143, A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC) (Protocol Version Date 04/16/19)
