

Adult CIRB - Late Phase Emphasis Meeting Agenda

March 3, 2022

I Continuing Review

A011401, Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer (Protocol Version Date 04/02/21)

II Continuing Review

A031501, Phase III Randomized Adjuvant Study of Pembrolizumab in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation (Protocol Version Date 10/25/21)

III Continuing Review

RTOG-0724, Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy (Protocol Version Date 02/04/22)

IV Continuing Review

S1418, A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of Pembrolizumab (MK-3475) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy (Protocol Version Date 10/15/21)

V New Study - Initial Review

NRG-GY026, A Phase II/III Study of Paclitaxel/Carboplatin Alone or Combined with Either Trastuzumab and Hyaluronidase-oysk (HERCEPTIN HYLECTA) or Pertuzumab Trastuzumab and Hyaluronidase-zzfx (PHESGO) in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma (Protocol Version Date 02/04/22)

VI Amendment

A081801, Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO) (Protocol Version Date 02/01/22)



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VII Amendment

S1900E, A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LungMAP Sub-Study) (Protocol Version Date 01/21/22)
