

Adult CIRB - Late Phase Emphasis Meeting Agenda

April 16, 2020

I Patient Recruitment Material/Info Docs ReReview

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

II Continuing Review

A011106, ALternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study (Protocol Version Date 07/11/19)

III Continuing Review

A031701, A Phase II Study of Dose-Dense Gemcitabine Plus Cisplatin (DDGC) in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations (Protocol Version Date 04/16/19)

IV Continuing Review

A151216, Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (Protocol Version Date 12/20/19)

V Continuing Review

NRG-GY005, A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer



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(COCOS) (Protocol Version Date 09/06/19)

VI Continuing Review

S1403, A Randomized Phase II Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC) (BI 1200.124) (Protocol Version Date 07/08/19)

VII Continuing Review

S1706, A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer (Protocol Version Date 05/20/19)

VIII Continuing Review

S1826, A Phase III, Randomized Study of Nivolumab (Opdivo) plus AVD or Brentuximab Vedotin (Adcetris) plus AVD in Patients (Age \geq 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma (Protocol Version Date 05/08/19)

IX New Study - Initial Review

A091902, A Multicenter Phase II Trial of Paclitaxel with and without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects with Angiosarcoma (Protocol Version Date 03/13/20)

X New Study - Initial Review

NRG-GI007, Phase I Trial with Expansion Cohort of OBP-301 (Telomelysin™) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal and Gastroesophageal Adenocarcinoma Who Are Not Candidates for Surgery (Protocol Version Date 03/30/20)

XI New Study - Initial Review



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S1929, Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) (Protocol Version Date 02/20/20)
