

Adult CIRB - Late Phase Emphasis Meeting Agenda

April 2, 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 04/16/19)

II Continuing Review

A021502, Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair (ATOMIC: Adjuvant Trial of Deficient Mismatch Repair in Colon Cancer) (Protocol Version Date 02/05/19)

III Continuing Review

A071601, Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas (Protocol Version Date 06/11/19)

IV Continuing Review

E1910, A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults (Protocol Version Date 12/03/19)

V Continuing Review

EA8153, Cabazitaxel with Abiraterone versus Abiraterone alone Randomized Trial for Extensive Disease following Docetaxel: the CHARTED2 Trial (Protocol Version Date 05/30/19)

VI Continuing Review



FOR THE NATIONAL CANCER INSTITUTE

NRG-GU007, Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I) (Protocol Version Date 06/18/19)

VII Continuing Review

NRG-GY016, A Phase II Study of MK-3475 (Pembrolizumab) (NSC #776864) + Epcadostat (NSC #766086) in Recurrent Clear Cell Carcinoma of the Ovary (Protocol Version Date 02/28/20)

VIII Continuing Review

NSABP-B-55, A Randomised, Double-blind, Parallel group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy (Protocol Version Date 07/27/18)

IX Continuing Review

S0777, A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant (Protocol Version Date 09/03/19)

X Continuing Review

S0819, A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) (Protocol Version Date 10/03/16)

XI Continuing Review

S1512, A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM) (Protocol Version Date 02/19/20)

XII Continuing Review

S1602, A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer (Protocol Version Date 07/22/19)

XIII New Study - Initial Review

A021806, A Phase III Trial of Perioperative versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer (Protocol Version Date 02/19/20)

XIV New Study - Initial Review

S1933, A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status (Protocol Version Date 02/07/20)

XV Amendment

A041501, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Protocol Version Date 02/14/20)
