

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 21, 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

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 02/27/20)

III Continuing Review

A031501, Phase III Randomized Adjuvant Study of MK-3475 (Pembrolizumab) in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation (Protocol Version Date 03/04/20)

IV Continuing Review

ABTC-1802, A Phase II Study of Binimetinib in Combination with Encorafenib in Adults with Recurrent BRAF V600-Mutated High-Grade Astrocytoma or other Primary Brain Tumor (Protocol Version Date 02/28/20)

V Continuing Review

NRG-HN005, A Randomized Phase II/III Trial of De-intensified Radiation Therapy for Patients with Early-Stage, p16-Positive, Non-Smoking Associated Oropharyngeal Cancer (Protocol Version Date 05/29/19)

VI Continuing Review

S1418, A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) 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 02/28/20)

VII New Study - Initial Review

A021804, A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma (Protocol Version Date 04/20/20)

VIII New Study - Initial Review

EA6192, A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients with Advanced Melanoma (PET-Stop) (Protocol Version Date 05/01/20)

IX New Study - Initial Review

NRG-BN007, A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab versus Temozolomide in Patients with Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma (Protocol Version Date 04/28/20)
