

Adult CIRB - Late Phase Emphasis Meeting Agenda

June 4, 2020

I Continuing Review

10272, A Phase II Multi-Institutional Trial to Evaluate Prostate Specific Membrane Antigen (PSMA)-Based PET Imaging of High Risk Prostate Cancer (Protocol Version Date 12/04/19)

II Continuing Review

EA2165, A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer (Protocol Version Date 07/29/19)

III Continuing Review

EA5161, Randomized Phase II Clinical Trial of Cisplatin/Carboplatin and Etoposide (CE) Alone or in Combination with Nivolumab as Frontline Therapy for Extensive Stage Small Cell Lung Cancer (ED-SCLC) (Protocol Version Date 03/29/19)

IV Continuing Review

EA6134, DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) A Phase III Trial (Protocol Version Date 12/16/19)

V Continuing Review

LUNGMAP, A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study) (Protocol Version Date 12/11/19)

VI Continuing Review



FOR THE NATIONAL CANCER INSTITUTE

NRG-GY004, A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Protocol Version Date 08/15/19)

VII Continuing Review

NRG-GY006, A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer (Protocol Version Date 11/25/19)

VIII Continuing Review

S1800A, A Phase II Randomized Study of Ramucirumab plus MK3475 (Pembrolizumab) versus Standard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study) (Protocol Version Date 02/21/20)

IX Continuing Review

S1802, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Protocol Version Date 09/11/19)

X Continuing Review

S1900A, A Phase II Study of Rucaparib in Patients with Genomic LOH High and/or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (LungMAP Sub-Study) (Protocol Version Date 03/03/20)

XI Continuing Review

S1900B, A Phase II Study of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (LungMAP Sub-Study) (Protocol Version Date 04/16/20)

XII Continuing Review

S1900C, A Phase II Study of Talazoparib plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (LungMAP Sub-Study) (Protocol Version Date 04/15/20)

XIII Continuing 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 02/14/20)

XIV 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)

XV New Study - Initial Review

NRG-LU007, RAnomized Phase II/III Trial Of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR trial (Protocol Version Date 04/24/20)

XVI 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 04/15/20)
