

Adult CIRB - Late Phase Emphasis Meeting Agenda

April 7, 2022

I Continuing Review

EA2165, A Randomized Phase III Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer (Protocol Version Date 02/10/21)

II 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 02/17/21)

III Continuing Review

EA6134, DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) A Phase III Trial (Protocol Version Date 11/19/21)

IV Continuing 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 10/25/21)

V Continuing Review

EA8191, Phase III Study of Local or Systemic Therapy INTensification DIrected by PET in Prostate CANcer Patients with Post-ProstaTEctomy Biochemical Recurrence (INDICATE) (Protocol Version Date 01/14/22)

VI 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 01/11/22)

VII Continuing Review

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 08/30/21)

VIII 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 02/17/21)

IX Continuing Review

NRG-LU007, RAnomized Phase II/III Trial Of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR trial (Protocol Version Date 06/02/21)

X Continuing Review

S1216, A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer (Protocol Version Date 04/07/17)

XI Continuing Review

S1800A, A Phase II Randomized Study of Ramucirumab plus Pembrolizumab (MK-3475) 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 10/15/21)

XII Continuing Review

S1800D, A Phase II/III Study of N-803 (ALT-803) Plus Pembrolizumab Versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy (Lung-MAP Non-Match Sub-Study) (Protocol Version Date 12/17/21)

XIII 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 11/18/21)

XIV 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 12/14/20)

XV 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 04/07/21)

XVI 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 04/07/21)

XVII Continuing Review

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 03/10/22)

XVIII New Study - Initial Review

NRG-GU012, Randomized Phase II Stereotactic Ablative Radiation Therapy (SABR) for Metastatic Unresected Renal Cell Carcinoma (RCC) Receiving Immunotherapy (SAMURAI) (Protocol Version Date 03/01/22)

XIX New Study - Initial Review

NRG-GY029, A Randomized Phase II Trial Comparing the Combination of PI3K Inhibitor Copanlisib (BAY 80-6946) and PARP Inhibitor Olaparib (AZD2281) to Standard Chemotherapy



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in Patients with Recurrent Platinum Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer who have Progressed through Prior PARP Inhibitor Therapy (Protocol Version Date 02/28/22)

XX New Study - Initial Review

S2107, Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab (NSC #748726) for Patients with Previously Treated, Microsatellite Stable, BRAFV600E Metastatic and/or Unresectable Colorectal Cancer (Protocol Version Date 02/18/22)

XXI Amendment

EA8185, Phase II Study of Bladder-Sparing Chemoradiation with Durvalumab in Clinical Stage III, Node Positive bladder Cancer (INSPIRE) (Protocol Version Date 02/18/22)
