

Adult CIRB - Late Phase Emphasis Meeting Agenda

March 2, 2023

I Amendment

EA5191, A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients with Previously Treated Non-Squamous NSCLC (Version Date 12/30/22)

II Continuing Review

EA6192, A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients with Advanced Melanoma (PET-Stop) (Version Date 01/31/23)

III Continuing Review

EA6134, DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) A Phase III Trial (Version Date 01/30/23)

IV 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 (Version Date 04/07/17)

V 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 (Version Date 02/17/21)

VI Continuing Review

NRG-LU007, RANdomized Phase II/III Trial Of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR trial (Version Date 11/09/22)

VII Continuing Review

NRG-GY027, Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Paclitaxel and Carboplatin with Ipatasertib as Initial Therapy of Ovarian Cancer PTMA 100805 (Version Date 05/11/22)

VIII Continuing Review

S1827, MRI Brain Surveillance Alone versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK) (Version Date 04/06/22)

IX 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) (Version Date 08/08/22)

X 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) (Version Date 08/04/22)

XI 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) (Version Date 06/15/22)

XII 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) (Version Date 02/28/22)

XIII Continuing Review

S1900B, A Phase II Study of Selpercatinib (LY3527723) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (LungMAP Sub-Study) (Version Date 06/27/22)

XIV 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) (Version Date 04/07/21)

XV 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) (Version Date 06/17/22)

XVI Continuing Review

S1900F, A Randomized Phase II Study of Carboplatin and Pemetrexed with or Without Selpercatinib (LY3527723) in Participants with Non-Squamous RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer and Progression of Disease on Prior RET Directed Therapy (Lung-MAP Sub-Study) (Version Date 11/14/22)

XVII Continuing Review

S1900G, A Randomized Phase II Study of INC280 (capmatinib) plus Osimertinib with or without Ramucirumab in Participants with EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)
(Version Date 01/17/23)
