

Adult CIRB - Late Phase Emphasis Meeting Agenda

February 1, 2024

I Amendment

A082002, A Randomized Phase II/III Trial of Modern Immunotherapy Based Systemic Therapy with or without SBRT for PD-L1-Negative, Advanced Non-small Cell Lung Cancer (Version Date 11/21/23)

II Continuing Review

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

III 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 08/18/23)

IV 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 12/22/23)

V Continuing Review

NRG-LU007, Randomized Phase II/III Trial Of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR trial (Version Date 10/18/23)

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) (Version Date 04/28/23)

VII 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)

VIII Continuing Review

S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Version Date 08/14/23)

IX 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 02/07/23)

X 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 07/10/23)

XI 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)

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 10/18/23)

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 09/27/23)

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 09/19/23)

XVI 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 09/27/23)
