

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 20, 2021

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 04/02/21)

II Continuing Review

A021602, Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo in Patients with Advanced Neuroendocrine Tumors After Progression on Prior Therapy (CABINET) (Protocol Version Date 07/24/20)

III Continuing Review

A021804, A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma (Protocol Version Date 10/23/20)

IV Continuing Review

A051301, A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype (Protocol Version Date 05/22/19)

V Continuing Review

A051701, Randomized Phase II/III Study of Venetoclax (ABT 199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double-Expressing Lymphomas (Protocol Version Date 08/03/20)

VI Continuing Review

EA2174, A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma (Protocol Version Date 01/20/21)

VII Continuing Review

EAA173, Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) (Protocol Version Date 10/22/20)

VIII Continuing Review

N0577, N0577 (CODEL): Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma (Protocol Version Date 10/22/18)

IX Continuing 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 02/09/21)

X Continuing Review

NRG-GU002, Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation following Radical Prostatectomy with or without Adjuvant Docetaxel (Protocol Version Date 08/26/19)

XI Continuing Review

NRG-GU005, Phase III IGRT and SBRT vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer (Protocol Version Date 01/23/20)

XII Continuing Review

NRG-GY021, A Phase II Randomized Trial of Olaparib Versus Olaparib Plus Tremelimumab In Platinum-Sensitive Recurrent Ovarian Cancer (Protocol Version Date 04/24/20)

XIII 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)

XIV Continuing Review

S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Protocol Version Date 01/19/21)

XV Continuing Review

S1931, Phase III Trial Of Immunotherapy-Based Combination Therapy With Or Without Cytoreductive Nephrectomy For Metastatic Renal Cell Carcinoma (Probe Trial) (Protocol Version Date 03/03/21)

XVI New Study - Initial Review

AMC-111, Impact of Behavior Modification Interventions and Lung Cancer Screening on Smoking Cessation in People Living with HIV: A Feasibility Study (Protocol Version Date 03/29/21)

XVII New Study - Initial Review

NRG-GY024, Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial (Protocol Version Date 04/26/21)

XVIII Amendment

EAA173, Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) (Protocol Version Date 04/16/21)

XIX Amendment

NRG-BR004, A Randomized, Double-Blind, Phase III Trial of Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (Protocol Version Date 03/30/21)