

Adult CIRB - Late Phase Emphasis Meeting Agenda

June 18, 2020

I Continuing Review

A021602, Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo in Patients with Advanced Neuroendocrine Tumors After Progression on Everolimus (CABINET) (Protocol Version Date 04/19/19)

II 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)

III 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 03/10/20)

IV 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 05/28/19)

V Continuing Review

EAA173, Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM) (Protocol Version Date 09/28/18)

VI 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)

VII 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)

VIII 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)

IX 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)

X Continuing Review

S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Protocol Version Date 05/08/20)

XI Continuing Review

S1612, A Randomized Phase II/III Trial of "Novel Therapeutics" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older (Protocol Version Date 09/06/18)

XII Continuing Review



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S1619, A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma (Protocol Version Date 03/20/19)

XIII New Study ReReview

EA8183, A Phase III Double Blinded Study of Early Intervention after RADICAL ProstaTEctomy with Androgen Deprivation Therapy with or without Darolutamide vs Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE) (Protocol Version Date 05/28/20)

XIV New Study - Initial Review

A011801, The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSEssment to Optimize Therapy in HER2-Positive Breast Cancer): CompassHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 Compared with T-DM1 and Tucatinb (Protocol Version Date 05/04/20)

XV New Study - Initial Review

NRG-HN007, An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma (Protocol Version Date 05/15/20)

XVI Amendment

E4412, A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma (Protocol Version Date 05/11/20)

XVII Amendment

EA9161, A Randomized Phase III Study of the addition of Venetoclax to Ibrutinib and Obinutuzumab versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 03/17/20)
