

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 5, 2022

I Continuing 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 and Placebo Compared with T-DM1 and Tucatinib (Protocol Version Date 02/09/22)

II Continuing Review

A091404, A Phase II Study of Enzalutamide (NSC# 766085) for Patients with Androgen Receptor Positive Salivary Cancers (Protocol Version Date 09/10/19)

III Continuing Review

EA6174, STAMP: Surgically Treated Adjuvant Merkel cell Carcinoma with Pembrolizumab, a Phase III Trial (Protocol Version Date 10/20/21)

IV Continuing Review

EA6191, The BAMB2 (BRAF, Autophagy, MEK inhibition in Melanoma) Study: A Randomized Double Blind Phase II Study of Dabrafenib and Trametinib with or without Hydroxychloroquine in Advanced BRAFV600E/K Melanoma with elevated LDH (Protocol Version Date 01/27/21)

V Continuing Review

EA8183, A Phase III Double Blinded Study of Early Intervention after RADICAL ProstaTEctomy with Androgen Deprivation Therapy with Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE) (Protocol Version Date 09/13/21)

VI Continuing Review

NRG-GY024, Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial (Protocol Version Date 01/28/22)

VII Continuing Review

RTOG-1216, Randomized Phase II/III Trial of Adjuvant Radiation Therapy with Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in Pathologic High-Risk, Squamous Cell Cancer of the Head and Neck (Protocol Version Date 06/02/21)

VIII Continuing Review

RTOG-1308, Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy For Inoperable Stage II-IIIB NSCLC (Protocol Version Date 10/06/21)

IX Continuing Review

S1922, Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI In Refractory Small Bowel Adenocarcinoma (Protocol Version Date 10/20/21)

X Amendment

A071801, Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared with Fractionated SRS (FSRS) for Resected Metastatic Brain Disease (Protocol Version Date 04/06/22)

XI Amendment

S1931, Phase III Trial Of Immunotherapy-Based Combination Therapy With Or Without Cytoreductive Nephrectomy For Metastatic Renal Cell Carcinoma (Probe Trial) (Protocol Version Date 04/11/22)
