

Adult CIRB - Late Phase Emphasis Meeting Agenda

April 15, 2021

I Continuing Review

A011401, Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer (Protocol Version Date 08/07/20)

II Continuing Review

A031501, Phase III Randomized Adjuvant Study of Pembrolizumab in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation (Protocol Version Date 09/22/20)

III Continuing Review

A031902, CASPAR - A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer (Protocol Version Date 10/12/20)

IV Continuing Review

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 08/21/20)

V Continuing Review

A091902, A Multicenter Phase II Trial of Paclitaxel with and without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects with Angiosarcoma (Protocol Version Date 02/17/21)



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VI Continuing Review

EA2182, A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE) (Protocol Version Date 01/08/20)

VII Continuing Review

NRG-GY018, A Phase III Randomized, Placebo-Controlled Study of Pembrolizumab (MK-3475, NSC #776864) in Addition to Paclitaxel and Carboplatin for Measurable Stage III or IVA, Stage IVB or Recurrent Endometrial Cancer (Protocol Version Date 12/08/20)

VIII Continuing Review

NRG-HN005, A Randomized Phase II/III Trial of De-intensified Radiation Therapy for Patients with Early-Stage, p16-Positive, Non-Smoking Associated Oropharyngeal Cancer (Protocol Version Date 02/16/21)

IX Continuing Review

S1418, A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of Pembrolizumab (MK-3475) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy (Protocol Version Date 10/21/20)

X New Study - Initial Review

AMC-112, Axicabtagene Ciloleucel in Relapsed or Refractory HIV-Associated Aggressive B-Cell Non-Hodgkin Lymphoma (Protocol Version Date 03/12/21)

XI New Study - Initial Review

S2005, A Phase II Randomized Study of Ibrutinib and Rituximab with or without Venetoclax in Previously Untreated Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL) (Protocol Version Date 03/23/21)

XII Memos

LUNGMAP, A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study) (Protocol Version Date 11/06/20)
