

Adult CIRB - Late Phase Emphasis Meeting Agenda

Thursday, March 1, 2018 9:00 am - 12:45 pm (Eastern)

I. Initial Review

CCTG CE.7, A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for 5-15 Brain Metastases (Protocol Version Date 01/31/18)

II. Initial Review

EA9171, Phase II Study of Adding the Anti-PD-1 Pembrolizumab to Tyrosine Kinase Inhibitors in Patients with Chronic Myeloid Leukemia and Persistently Detectable Minimal Residual Disease (Protocol Version Date 01/29/18)

III. Continuing Review

E2905, Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia (Protocol Version Date 03/10/17)

IV. Continuing Review

E4402, Randomized Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Patients with Low Tumor Burden Indolent Non-Hodgkin's Lymphoma (Protocol Version Date 04/23/14 Update Date 03/11/15)

V. Continuing Review

A011502, A Randomized Phase III Double Blinded Placebo-Controlled Trial of Aspirin as Adjuvant Therapy for HER2 Negative Breast Cancer: The ABC Trial (Protocol Version Date 01/10/18)

VI. Continuing Review

\$1616, A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent (Protocol Version Date 11/16/17)

VII. Continuing Review

CALGB-10701, A Phase II Study of Dasatinib (Sprycel®) (IND #73969, NSC #732517) as Primary Therapy Followed by Transplantation for Adults >/= 18 Years with Newly Diagnosed Ph+ Acute Lymphoblastic Leukemia by CALGB, ECOG and SWOG (Protocol Version Date 02/21/17)

VIII. Continuing Review

NRG-GY009, A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab (IND #134427) versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Protocol Version Date 08/21/17)

IX. Continuing Review

NRG-GI002, A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer (Protocol Version Date 08/22/16 Update Date 01/09/17)

X. Continuing Review

NRG-GI004, Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer (Protocol Version Date 11/20/17)

XI. Continuing Review

\$1613, A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification (Protocol Version Date 11/20/17)