

Adult CIRB - Late Phase Emphasis Meeting Agenda

September 16, 2021

I Continuing Review

A071702, A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermuted Recurrent Glioblastoma (Protocol Version Date 02/12/21)

II Continuing Review

A151804, Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events (Protocol Version Date 10/28/20)

III Continuing Review

NRG-BN009, Phase III Trial of Salvage Stereotactic Radiosurgery (SRS) or SRS + Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for First or Second Distant Brain Relapse after Upfront SRS with Brain Metastasis Velocity ≥ 4 Brain Metastases/Year (Protocol Version Date 11/11/20)

IV Continuing Review

NRG-GU008, Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer after Radical Prostatectomy (INNOVATE) Intensifying treatment for Node positive prostate cancer by Varying the hormonal Therapy (Protocol Version Date 09/18/20)

V Continuing Review

S1701, A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma (Protocol Version Date 01/08/21)

VI New Study - Initial Review

NRG-GU011, A Phase II Double-Blinded, Placebo Controlled Trial of Prostate Oligometastatic Radiotherapy with or without Androgen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG PROMETHEAN) (Protocol Version Date 08/05/21)

VII Amendment

S1712, A Randomized Phase II Study of Ruxolitinib (NSC-752295) in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia (CML) Patients with Molecular Evidence of Disease (Protocol Version Date 08/11/21)
