

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 18, 2022

I Continuing Review

A071702, A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermuted Recurrent WHO Grade 4 Glioma (Protocol Version Date 05/27/22)

II Continuing Review

A151804, Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events (Protocol Version Date 09/27/21)

III Continuing Review

E5508, Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC (Protocol Version Date 10/12/18)

IV 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)

V Continuing Review

NRG-GU008, Randomized Phase III Trial Incorporating Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer after Radical Prostatectomy (INNOVATE*) (Protocol Version Date 09/15/21)

VI Continuing Review

NRG-GU010, Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE) (Protocol Version Date 10/11/21)

VII Continuing Review

NRG-HN009, Randomized Phase II/III Trial of Radiation with High-Dose Cisplatin (100 mg/m²) Every Three Weeks Versus Radiation with Low-Dose Weekly Cisplatin (40 mg/m²) for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN) (Protocol Version Date 10/04/21)

VIII Continuing Review

S1803, Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC STUDY) (Protocol Version Date 06/07/22)
