

Adult CIRB - Late Phase Emphasis Meeting Agenda

December 16, 2021

I Continuing Review

NRG-HN001, Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA) (Protocol Version Date 06/28/21)

II New Study - Initial Review

S2101, Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Patients with Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study (Protocol Version Date 10/18/21)

III Amendment

EA1181, (CompassHER2-pCR): Preoperative THP and postoperative HP in patients who achieve a pathologic complete response (Protocol Version Date 11/15/21)

III Amendment

S1802, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Protocol Version Date 11/18/21)
