

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 21, 2020

I Amendment Prior to Activation

10334, BLockade of PD-1 Added to Standard Therapy to target Measurable Residual Disease in Acute Myeloid Leukemia 2 (BLAST MRD AML-2): A randomized Phase 2 Study of the Venetoclax, Azacitidine, and Pembrolizumab (VAP) Versus Venetoclax and Azacitidine as First Line Therapy in Older Patients with Acute Myeloid Leukemia (AML) who are Ineligible or who Refuse Intensive Chemotherapy (Protocol Version Date 06/09/20)

II Continuing Review

10211, A Phase 2 Single-Arm Study of M6620 in Combination with Irinotecan in Patients with Progressive TP53 Mutant Gastric and Gastro-Esophageal Junction Cancer (Protocol Version Date 06/10/2020)

III Continuing Review

9681, A Phase 1 Study of Cabozantinib plus Nivolumab (CaboNivo) Alone or in Combination with Ipilimumab (CaboNivoIpi) in Patients with Advanced/Metastatic Urothelial Carcinoma and other Genitourinary Tumors. (Protocol Version Date 09/25/19)

IV Continuing Review

NRG-DT001, A Phase Ib Trial of Neoadjuvant AMG 232 (KRT-232) Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma (STS) (Protocol Version Date 01/28/2020)

V New Study - Initial Review

10389, A Phase 1 Trial Combining WEE1 Inhibitor Adavosertib (AZD1775) with Radiation Therapy for Metastatic or Inoperable and Ineligible for Definitive Chemoradiation Esophageal and Gastroesophageal Junction Cancer (Protocol Version Date 06/08/20)

VI New Study - Initial Review

10401, A Phase 0 window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Protocol Version Date 06/16/20)

VII Amendment

10170, A Phase 2 Study of AZD1775 in SETD2-Deficient Advanced Solid Tumor Malignancies (Protocol Version Date 06/05/20)
