

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 6, 2021

I Continuing Review

10136, A Phase 2 Study Of AZD1775, A WEE1 Inhibitor, In Patients With CCNE1 Amplification (Protocol Version Date 06/02/20)

II Continuing Review

10145, Phase 1b Study Of Copanlisib In Combination With Nivolumab Or With Nivolumab And Ipilimumab (Protocol Version Date 02/16/21)

III Continuing Review

10186, A Phase I/II Study of Nivolumab plus or minus Ipilimumab in Combination with Multi-fraction Stereotactic Radiosurgery for Recurrent High-grade Radiation-relapsed Meningioma (Protocol Version Date 05/25/21)

IV Continuing Review

10291, A Phase 1b Study of Berzosertib in Combination with Radiation Therapy to Overcome Therapeutic Resistance in Chemotherapy Resistant Triple Negative and Estrogen and/or Progesterone Receptor Positive, HER2 Negative Breast Cancer (Protocol Version Date 12/03/20)

V Continuing 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 08/26/20)

VI Continuing Review

10401, A Phase 0 window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Protocol Version Date 01/06/21)

VII Continuing Review

10404, A Phase 1 Trial of the ATR Inhibitor BAY 1895344 in Combination with Cisplatin and with Cisplatin Plus Gemcitabine in Advanced Solid Tumors with an Emphasis on Urothelial Carcinoma (Protocol Version Date 12/18/20)

VIII 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 02/22/21)

IX New Study - Initial Review

10476, A Randomized Phase 2 Study of Combination Atezolizumab and CDX-1127 (Varlilumab) With or Without Addition of Cobimetinib in Previously Treated Unresectable Biliary Tract Cancers (Protocol Version Date 05/24/21)

X New Study - Initial Review

AMC-110, Risk-Adapted Therapy for HIV-Associated Anal Cancer (Protocol Version Date 05/13/21)
