

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 7, 2022

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 02/24/22)

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 01/13/22)

VI Continuing Review

10401, A Phase 0 window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Protocol Version Date 01/19/22)

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 04/12/22)

VIII Continuing Review

9892, Phase I Dose-Escalation Bioavailability Study of Oral Triapine in Combination with Concurrent Chemoradiation for Locally Advanced Cervical Cancer (LACC) and Vaginal Cancer (Protocol Version Date 03/17/21)

IX 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 12/01/21)

X New Study - Initial Review

10464, A Phase 1 Study of Olaparib in Combination with Durvalumab (MEDI4736) and Concurrent Radiation Therapy Following First-Line Chemotherapy in Locally Advanced Unresectable Pancreatic Cancer (Protocol Version Date 05/03/22)

XI Amendment

10217, A Phase 1b Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients with Advanced Solid Tumors (Protocol Version Date 04/04/22)

XII Amendment

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Protocol Version Date 04/13/22)

XIII Amendment

10434, Randomized Phase 2 Study of CPX-351 + Pomalidomide versus CPX-351 in Newly Diagnosed AML with MDS-Related Changes (Protocol Version Date 04/14/22)
