

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 15, 2022

I New Study - Initial Review

10522, A Phase 1 Clinical Trial of CA-4948 in Combination with Gemcitabine and Nab-Paclitaxel in Metastatic or Unresectable Pancreatic Ductal Carcinoma (Version Date 10/11/22)

II New Study - Initial Review

10538, Venetoclax In Combination with ASTX727, an All-ORal TherapY for Chronic Myelomonocytic Leukemia and Other MDS/MPN with Excess Blasts (VICTORY-MDS/MPN): a Randomized, Phase 2 trial (Version Date 07/19/22)

III Amendment

10020, A Phase II Open-Label, Randomized Study of PARP Inhibition (olaparib) Either Alone or in Combination with Anti-PD-L1 Therapy (atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-positive Breast Cancer (Version Date 10/10/22)

IV Amendment

10382, A Phase I/II Trial Evaluating the Safety and Efficacy of Eribulin in Combination with Copanlisib in Patients with Metastatic Triple Negative Breast Cancer (Version Date 09/21/22)

V Amendment

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and Telaglenastat (CB-839) HCl in Advanced NSCLC Patients (Version Date 10/13/22)

VI Continuing Review

10076, A Phase 1 Dose-Escalation and Exploratory Dose Expansion Study of KRT-232 (AMG 232) in Combination with Carfilzomib, Lenalidomide, and Dexamethasone in Relapsed and/or Refractory Myeloma (Version Date 01/24/22)

VII Continuing Review

10358, Phase 1/1B study of DS-8201a in combination with ATR Inhibition (AZD6738) in advanced solid tumors with HER2 expression (DASH Trial) (Version Date 02/17/22)

VIII Continuing Review

10217, A Phase 1b Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients with Advanced Solid Tumors (Version Date 07/29/22)

IX Continuing Review

10388, A Phase I Trial of Triapine and Lutetium Lu 177 Dotatate in Combination for Well-Differentiated Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Version Date 09/29/22)

X Continuing Review

10490, Rapid Analysis and Response Evaluation of Combination Anti-neoplastic Agents in Rare Tumors (RARE CANCER) Trial: RARE 2 Talazoparib and Temozolomide (Version Date 07/01/22)

XI Continuing Review

10347, A phase I study with an expansion cohort of duvelisib and nivolumab in mycosis fungoides (MF) and Sézary syndrome (SS) (Version Date 05/06/22)
