

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 19, 2020

I Continuing Review ReReview

9706, Randomized phase II study to assess the role of Nivolumab as single agent to eliminate minimal residual disease and maintain remission in acute myelogenous leukemia (AML) patients after chemotherapy (REMAIN Trial) (Protocol Version Date 09/24/19)

II Continuing Review

10070, Phase 1/2 Study of Navitoclax Plus Vistusertib in Patients with Relapsed Small Cell Lung Cancer (SCLC) and Other Solid Tumors (Protocol Version Date 08/20/19)

III Continuing Review

10191, A Phase 2 Study of M6620 in Combination with Carboplatin compared with Docetaxel in Combination with Carboplatin in Metastatic Castration-Resistant Prostate Cancer (Protocol Version Date 03/24/20)

IV Continuing Review

10264, The PRIME Trial: PARP Inhibition in IDH Mutant Effectiveness Trial. A Phase II Study of Olaparib in Isocitrate Dehydrogenase (IDH) Mutant Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome (Protocol Version Date 01/16/20)

V Continuing Review

10266, A Phase 2 Study of MLN4924 (pevonedistat) in Combination with Carboplatin and Paclitaxel in Advanced NSCLC Previously Treated with Immunotherapy (Protocol Version Date 11/19/19)



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VI Continuing Review

9903, A Phase 1B Study of AZD9291 in Combination with Navitoclax in EGFR-mutant Non-Small Cell Lung Cancer Following Resistance to Initial EGFR Kinase Inhibitor (Protocol Version Date 10/03/19)

VII Continuing Review

ABTC-1701, Pilot Surgical PK Study of Bemcentinib in Recurrent Glioblastoma Patients (Protocol Version Date 04/30/19)

VIII Amendment

10146, Randomized phase 2 clinical trial of nab-paclitaxel + MEDI4736 (durvalumab) + tremelimumab + neoantigen vaccine vs. nab-paclitaxel + MEDI4736 (durvalumab) + tremelimumab in patients with metastatic triple negative breast cancer (Protocol Version Date 04/09/20)
