

Adult CIRB - Early Phase Emphasis Meeting Agenda

October 20, 2020

I Continuing Review ReReview

9952, Phase 1 Trial to Determine the Recommended Phase 2 Dose (RP2D) of M6620 (VX-970) When Combined with Whole Brain Radiotherapy (WBRT) in Patients with Brain Metastases from Lung Cancer (Protocol Version Date 07/07/20)

II Continuing Review

10021, A Phase 2 Study of MEDI4736(durvalumab) and Tremelimumab Alone or in Combination with High or Low-Dose Radiation in Metastatic Colorectal and NSCLC (Protocol Version Date 08/30/19)

III Continuing Review

10030, A phase 1 study of blinatumomab in combination with checkpoint inhibitor(s) of PD-1 (nivolumab) or both PD-1 (nivolumab) and CTLA-4 (ipilimumab) in patients with poor-risk, relapsed or refractory CD19+ precursor B-lymphoblastic leukemia (Protocol Version Date 04/23/20)

IV Continuing Review

10056, A Phase 2 Study of Talimogene Laherparepvec (T-VEC) and Radiation in Localized Soft Tissue Sarcoma (Protocol Version Date 09/24/20)

V Continuing Review

10107, Phase 1 Safety Run-In and Phase 2 Randomized Clinical Trial of Anetumab Ravtansine and Pembrolizumab (MK-3475) Compared to Pembrolizumab Alone for Mesothelin-Positive Malignant Pleural Mesothelioma (Protocol Version Date 09/25/20)

VI Continuing Review

10212, A Phase 1b/2 study of Pinometostat in Combination with standard induction chemotherapy in newly diagnosed Acute Myeloid Leukemia with MLL rearrangement (Protocol Version Date 03/26/19)

VII Continuing Review

10247, A Randomized Phase II Trial of MLN4924 (Pevonedistat) with Azacitidine versus Azacitidine in Adult Relapsed or Refractory Acute Myeloid Leukemia (Protocol Version Date 09/18/20)

VIII Continuing Review

ABTC-1801, Phase I/II Study of Pamiparib (BGB-290) with Temozolomide in Recurrent Gliomas with IDH1/2 Mutations (Protocol Version Date 07/29/20)

IX New Study ReReview

10406, Phase 1/1b Trial of ATR Inhibitor BAY 1895344 in Combination with FOLFIRI in GI Malignancies with a Focus on Metastatic Colorectal and Gastric/Gastroesophageal Cancers (Protocol Version Date 09/28/20)

X New Study - Initial Review

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Protocol Version Date 09/18/20)

XI New Study - Initial Review

10402, BAY 1895344 Plus Topoisomerase-1 (Top1) Inhibitors in Patients with Advanced Solid Tumors, Phase I Studies with Expansion Cohorts in Small Cell Lung Carcinoma (SCLC), Poorly Differentiated Neuroendocrine Carcinoma (PD-NEC) and Pancreatic Adenocarcinoma (PDA) (Protocol Version Date 09/09/20)



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XII New Study - Initial Review

10405, Phase I Trial of BAY 1895344 ATR Inhibitor Combined with Stereotactic Body Radiation Therapy and Pembrolizumab for Recurrent Head and Neck Squamous Cell Carcinoma (Protocol Version Date 09/09/20)

XIII Amendment

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 09/21/20)
