

Adult CIRB - Early Phase Emphasis Meeting Agenda

September 20, 2022

I Continuing Review

10026, A Phase 1 Study of Ipilimumab in Combination with Decitabine in Relapsed or Refractory Myelodysplastic Syndrome/Acute Myeloid Leukemia (Protocol Version Date 06/30/20)

II Continuing Review

10131, A Phase 1 Study of AZD8186 in Combination with Docetaxel in patients with PTEN mutated or PIK3CB mutated advanced solid tumors, potentially amenable to docetaxel (Protocol Version Date 05/20/21)

III Continuing Review

10221, A Phase I/II Biomarker Driven Combination Trial of Copanlisib and Immune Checkpoint Inhibitors in patients with advanced solid tumors (Protocol Version Date 09/15/21)

IV Continuing Review

10246, A Phase 1 Study of MLN4924 (pevonedistat) and Belinostat in Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome (Protocol Version Date 02/16/22)

V Continuing Review

10366, A Phase 1/2 Study of M3814 (peposertib) in Combination with Hypofractionated Radiotherapy for the Treatment of Locally Advanced Pancreatic Adenocarcinoma (Protocol Version Date 06/23/21)

VI Continuing 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 04/13/22)

VII Continuing Review

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 09/22/21)

VIII Continuing Review

10410, A Phase 1 Study of IPdR in Combination with Capecitabine and Radiotherapy in Rectal Cancer (Protocol Version Date 06/02/22)

IX Continuing Review

10411, Phase 2 Study of Rogaratinib (BAY 1163877) in the Treatment of Patients with Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-deficient Gastrointestinal Stromal Tumor (GIST) (Protocol Version Date 06/30/22)

X Continuing Review

A051901, Phase I Trial of Methotrexate, Rituximab, Lenalidomide, and Nivolumab (NIVO-MR2) Induction Followed by Lenalidomide and Nivolumab Maintenance in Primary CNS Lymphoma (Protocol Version Date 03/07/22)

XI New Study - Initial Review

EAY191-E4, A ComboMATCH Treatment Trial ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients with Prior Taxane-Treated Solid Tumors (Protocol Version Date 08/10/22)

XII New Study - Initial Review

EAY191-N2, A ComboMATCH Treatment Trial EAY191-N2: Phase 2 Trial of Fulvestrant and Binimetinib in Patients with Hormone Receptor-Positive Metastatic Breast Cancer with a Frameshift or Nonsense Mutation or Genomic Deletion in NF1 (Protocol Version Date 08/05/22)

XIII New Study - Initial Review

EAY191-S3, Phase 2 Study of Paclitaxel + Ipatasertib in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors (A ComboMATCH Treatment Trial) (Protocol Version Date 08/12/22)



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XIV Amendment

10384, A Phase 1b/2 Study of Hu5F9-G4 (magrolimab) in Combination with Mogamulizumab in Relapsed/Refractory Treated T- cell Lymphoma (Protocol Version Date 08/09/22)
