

**Adult CIRB - Early Phase Emphasis Meeting Agenda**

**August 15, 2023**

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**I Amendment**

**10495**, Phase I Trial of DS-8201a (Trastuzumab Deruxtecan) in Combination with Neratinib in Solid Tumors with HER2 Alterations (Version Date 06/15/23)

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**II Continuing Review**

**10366**, A Phase 1/2 Study of M3814 (peposertib) in Combination with Hypofractionated Radiotherapy for the Treatment of Locally Advanced Pancreatic Adenocarcinoma (Version Date 01/10/23)

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**III 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 (Version Date 05/30/23)

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**IV 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 (Version Date 03/16/23)

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**V 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) (Version Date 03/07/23)

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## **VI Continuing Review**

**EAY191-N4**, Molecular Analysis for Combination Therapy Choice (ComboMATCH) EAY191-N4: A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers A ComboMATCH Treatment Trial (Version Date 07/11/23)

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## **VII 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 (Version Date 05/04/23)

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