

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 5, 2026

I New Study - Initial Review

10741, A Phase 2 Study of Microsatellite Stable Colorectal Cancer (Stage 2 or 3) with Radiographic Occult Molecular Residual Disease Treated with Botensilimab (AGEN1181; Bot) plus Balstilimab (AGEN2034, Bal) After Established Definitive Therapy (COMBAT Study) (Version Date 03/05/26)

II Amendment

10527, A Molecularly Driven Phase 1b Dose Escalation and Dose Expansion Study of the DNA-PK Inhibitor Peposertib (M3814) in Combination with the ATR Inhibitor Tuvusertib (M1774) (Version Date 03/30/26)

III Amendment

A071401, Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations (Version Date 03/31/26)

IV Continuing Review

10237, A Phase 1 Study of TAK-243 for Relapsed or Refractory Acute Myeloid Leukemia or Myelodysplastic Syndromes with Increased Blasts (Version Date 10/05/25)

V Continuing Review

10366, A Phase 1/Randomized Phase 2 Study of M3814 (peposertib) in Combination with Hypofractionated Radiotherapy for the Treatment of Locally Advanced Pancreatic Adenocarcinoma (Version Date 11/06/25)

VI 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 04/04/25)

VII Continuing Review

10554, Phase 1 Study of Trastuzumab Deruxtecan (DS-8201a) in Combination with Azenosertib (ZN-c3) in HER2-Expressing/Amplified Gastric/Gastroesophageal Junction Cancer and Other Solid Tumors (Version Date 11/03/25)

VIII Continuing Review

10592, A Randomized Phase 2 Study of ATR inhibition in advanced PD-(L)1-refractory Merkel cell carcinoma: The MATRiX Trial (Version Date 03/18/26)

IX Continuing Review

10620, A Phase 1b Trial of Teclistamab in Combination with Iberdomide for Relapsed/Refractory Multiple Myeloma (Version Date 04/08/26)

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 (Version Date 01/05/26)
