

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 3, 2025

I New Study - Initial Review

10666, A First-in-Human Dose-Finding Phase I Study of Bone-targeted High Specific Activity Stannic-117m Pentatate (Sn-117m-DTPA) in Solid Tumors with Skeletal Metastases (Version Date 04/16/25)

II New Study - Initial Review

10706, A Phase 2 Window of Opportunity Trial of Neoadjuvant Agonistic Anti-CD40 Antibody CDX-1140 and Cemiplimab (REGN2810) in AJCC Stage III-IV Head and Neck Cancer Patients Prior to Surgery (Version Date 03/25/25)

III 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 03/31/25)

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 09/16/24)

V Continuing Review

10554, Phase 1 Study of Trastuzumab Deruxtecan (DS-8201a) in Combination with Azenosertib (ZN-c3) in HER2-Expressing/Amplified Cyclin E-Amplified Gastric/Gastroesophageal Junction Cancer and Other Solid Tumors with HER2 Expression (Version Date 11/19/24)

VI Continuing Review

10620, A Phase 1b Trial of Teclistamab in Combination with Iberdomide for Relapsed/Refractory Multiple Myeloma (Version Date 03/05/25)

VII 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 11/26/24)
