

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 4, 2026

I Continuing Review

10479, A Phase I Dose Escalation-Expansion Trial of Sunitinib Malate plus Lutetium Lu 177 Dotatate (Lutathera) in Somatostatin Receptor Positive Pancreatic Neuroendocrine Tumors (Version Date 02/09/26)

II Continuing Review

10605, A Phase 1 Study of ZEN003694 (ZEN-3694) in Combination with Cetuximab and Encorafenib in Patients with Refractory BRAF V600E Metastatic Colorectal Cancer (Version Date 07/21/26)

III Continuing Review

10660, A Phase I/II Study Evaluating the Safety, Tolerability, and Efficacy of Sotorasib Plus Trastuzumab Deruxtecan in Patients with Advanced Non-Small Cell Lung Cancer with a KRASG12C Mutation (Version Date 12/31/25)

IV Continuing Review

10667, Pilot Study of Pidnarulex Pharmacodynamics in Patients with Advanced Solid Tumors (Version Date 02/04/26)

V Continuing Review

EAY191-E5, A ComboMATCH Treatment Trial ComboMATCH Treatment Trial E5: A Randomized Phase II Study of AMG 510 (Sotorasib) with or without Panitumumab in Advanced Solid Tumors (Version Date 01/07/26)

VI Continuing Review

10496, A Phase 2 Study of Ipatasertib in Combination with Pembrolizumab for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (Version Date 08/07/25)
