

Adult CIRB - Early Phase Emphasis Meeting Agenda

September 2, 2025

I New Study - Initial Review

10716, A Phase 1 and Randomized Phase 2 Trial of Pidnarulex (CX-5461) and Cemiplimab (REGN2810) in Refractory Microsatellite Stable Colorectal Cancer (Version Date 08/09/25)

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 02/24/25)

III Amendment

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 07/21/25)

IV 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 05/28/25)

V 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)

VI Continuing Review

10667, Pilot Study of Pidnarulex Pharmacodynamics in Patients with Advanced Solid Tumors (Version Date 05/07/25)

VII 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 02/29/24)
