

Adult CIRB - Late Phase Emphasis Meeting Agenda

January 4, 2024

I Continuing Review

NRG-GY026, A Phase II/III study of paclitaxel/carboplatin alone or combined with either trastuzumab and hyaluronidase-oysk (HERCEPTIN HYLECTA) or pertuzumab trastuzumab and hyaluronidase-zzfx (PHESGO) in HER2 positive, stage I-IV endometrial serous carcinoma or carcinosarcoma (Version Date 12/06/22)

II Amendment

NRG-GY026, A Phase II/III study of paclitaxel/carboplatin alone or combined with either trastuzumab and hyaluronidase-oysk (HERCEPTIN HYLECTA) or pertuzumab trastuzumab and hyaluronidase-zzfx (PHESGO) in HER2 positive, stage I-IV endometrial serous carcinoma or carcinosarcoma (Version Date 11/20/23)

III Amendment

S1937, A Phase III Randomized Trial of Eribulin (NSC #707389) with Gemcitabine versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy (Version Date 12/06/23)

IV Continuing Review

A011401, Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer (Version Date 04/20/22)

V Continuing Review

EA2182, A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE) (Version Date 09/19/23)

VI Continuing Review

S1802, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Version Date 11/18/21)

VII Continuing Review

S1931, Phase III Trial Of Immunotherapy-Based Combination Therapy With Or Without Cytoreductive Nephrectomy For Metastatic Renal Cell Carcinoma (Probe Trial) (Version Date 10/05/23)
