

Adult CIRB - Late Phase Emphasis Meeting Agenda

February 17, 2022

I Continuing Review

A021806, A Phase III Trial of Perioperative versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer (Protocol Version Date 05/04/20)

II Continuing Review

A031701, A Phase II Study of Gemcitabine Plus Cisplatin Chemotherapy in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations (Protocol Version Date 01/13/21)

III Continuing Review

A051902, A Randomized Phase II Study of CHO(E)P vs CC-486-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-Cell Lymphomas (Protocol Version Date 07/02/21)

IV Review

A081105, Randomized Study of Erlotinib Vs Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC) (Protocol Version Date 01/20/21)

V Continuing Review

E3A06, Randomized Phase III Trial of Lenalidomide versus Observation Alone In Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma (Protocol Version Date 09/26/19)

VI Continuing Review

EA5191, A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients with Previously Treated Non-Squamous NSCLC (Protocol Version Date 04/21/21)



VII Continuing Review

NRG-GI007, Phase I Trial with Expansion Cohort of OBP-301 (TelomelysinTM) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal and Gastroesophageal Adenocarcinoma Who Are Not Candidates for Surgery (Protocol Version Date 01/11/22)

VIII Continuing Review

NRG-GU007, Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I) (Protocol Version Date 11/09/20)

IX Continuing Review

NRG-GY018, A Phase III Randomized, Placebo-Controlled Study of Pembrolizumab (MK-3475, NSC #776864) in Addition to Paclitaxel and Carboplatin for Measurable Stage III or IVA, Stage IVB or Recurrent Endometrial Cancer (Protocol Version Date 10/06/21)

X Continuing Review

RTOG-0724, Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy (Protocol Version Date 02/04/22)

XI Continuing Review

RTOG-1112, Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma (Protocol Version Date 09/14/20)

XII Continuing Review

S0819, A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) (Protocol Version Date 10/03/16)

XIII Continuing Review

S1706, A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer (Protocol Version Date 09/02/21)



XIV Amendment

 $NRG\text{-}GU005, \ Phase \ III \ IGRT \ and \ SBRT \ vs \ IGRT \ and \ Hypofractionated \ IMRT \ for \ Localized \ Intermediate \ Risk \ Prostate \ Cancer \ (Protocol \ Version \ Date \ 01/14/22)$