

Adult CIRB - Late Phase Emphasis Meeting Agenda

March 19, 2020

I Continuing Review

9149, Molecular Profiling-based Assignment of Cancer Therapy for Patients With Advanced Solid Tumors (Protocol Version Date 01/07/20)

II Continuing Review

A041202, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (\geq 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 03/20/19)

III Continuing Review

EA8143, A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC) (Protocol Version Date 04/16/19)

IV Continuing Review

EAF151, Change in Relative Cerebral Blood Volume as a Biomarker for Early Response to Bevacizumab in Patients with Recurrent Glioblastoma (Protocol Version Date 02/01/18)

V Continuing Review

N1048, N1048 (PROSPECT**): A Phase II/III Trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision (Protocol Version Date 10/03/18)

VI Continuing Review

NRG-BR002, A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer (Protocol Version Date 07/11/18)

VII Continuing Review

NRG-GY012, A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer (Protocol Version Date 06/11/19)

VIII Continuing Review

S1207, Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e3 Breast Cancer Study - evaluating everolimus with endocrine therapy (Protocol Version Date 10/24/18)

IX New Study - Initial 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 02/13/20)

X New Study - Initial Review

NRG-HN006, Randomized Phase II/III Trial of Sentinel Lymph Node Biopsy versus Elective Neck Dissection for Early-Stage Oral Cavity Cancer (Protocol Version Date 02/14/20)

XI New Study - Initial Review

S1918, A Phase II/III Randomized Study of R-miniCHOP with or without CC-486 (Oral Azacitidine) in Patients Age 75 Years or Older with Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIb Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-Cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements (Protocol Version Date 02/06/20)

XII Amendment

A011202, A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy (Protocol Version Date 01/31/20)

XIII Amendment

A041501, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Protocol Version Date 02/14/20)
