



Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, May 18, 2017
9:00 am – 11:15 am (Eastern)

I Amendment Review – Revision 9

S1400, A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-Map) (Protocol Version Date 04/12/17)

II Amendment Review – Addendum 1 (Amendment Prior To Activation).

EA4151, A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease-Negative First Complete Remission (Protocol Version Date 04/13/17)

III Continuing Review

GOG-0213, A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel (Or Gemcitabine) Alone or in Combination with Bevacizumab (NSC #704865, IND #113912) followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer. NCI-Supplied Agents: Bevacizumab (NSC #704865, IND #113912) (12/19/2011) (10/01/12) NCT# 00565851 (Protocol Version Date 09/13/16)

IV Continuing Review

S1007, A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial RX for Positive Node, Endocrine Responsive Breast Cancer (Protocol Version Date 11/09/15)

V Continuing Review

E1505, A Phase III Randomized Trial of Adjuvant Chemotherapy with or without Bevacizumab for Patients with Completely Resected Stage IB (≥ 4 cm) -IIIA Non-Small Cell Lung Cancer (NSCLC) (Protocol Version Date 12/19/14)

VI Continuing Review

EA1131, A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy (Protocol Version Date 05/16/16)

VII Continuing Review

S1505, A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/NAB-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma (Protocol Version Date 08/01/16)

VIII **Continuing Review**

E2108, A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer (Protocol Version Date 03/10/15)

IX **Continuing Review**

CALGB-40503, Endocrine Therapy with or without ANTI-VEGF Therapy: A Randomized, Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab (NSC 704865; IND 7921) for Women with Hormone Receptor-Positive Advanced Breast Cancer (Protocol Version Date 09/30/16)

X **Continuing Review**

RTOG-0920, A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer (Protocol Version Date 01/25/16)

XI **Continuing Review**

NRG-HN001, Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA) (Protocol Version Date 04/14/16)

XII **Reports of Expedited Reviews April 2017**

- Late Phase Emphasis CIRB Local Context Subcommittee Report
 - Expedited Reviews and Study Acknowledgements
 - Study Activation Acknowledgements
 - Amendment Activation Acknowledgements
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